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Rebalancing TRIPS

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REBALANCING TRIPS

*Molly Land**

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INTRODUCTION

Application of the World Trade Organization's (WTO) dispute resolution procedures to the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement) has provoked a variety of reactions over time. At its inception, the decision to enforce the treaty through the WTO's dispute resolution process was widely viewed as a loss for developing countries. Many feared it would lead to an explosion of litigation against developing countries and cause distortions in domestic intellectual property (IP) policy making.¹ More recent scholarship, however, has argued that these fears were unfounded. Few disputes before WTO panels have involved violations of the TRIPS Agreement, even fewer have been brought against developing countries, and none of those have authorized the withdrawal of trade concessions.²

* Associate Professor of Law, New York Law School. My thanks to Rebecca Bratspies, Elizabeth Chambliss, Harlan Cohen, Evan Criddle, Rochelle Dreyfuss, Steve Ellmann, Doni Gewirtzman, Larry Helfer, Patricia Judd, Joel Trachtman, and Peter Yu for very helpful feedback in the research and drafting of this Article. Earlier drafts benefited greatly from discussions on a "New Voices" panel at the 2011 ASIL Annual Meeting, the faculty workshop at New York Law School, and a 2010 JILSA workshop. Christopher Bruno, Beulah Chou, Robert Habermann, Zalika Pierre, and David Rodrigues provided excellent research assistance.

1. U.N. CONF. ON TRADE & DEV.-INT'L CTR. FOR TRADE & SUST. DEV. [UNCTAD-ICTSD], RESOURCE BOOK ON TRIPS AND DEVELOPMENT 659-64 (2005) [hereinafter TRIPS RESOURCE BOOK]; see also Joost Pauwelyn, *The Dog that Barked but Didn't Bite: 15 Years of Intellectual Property Disputes at the WTO*, 1 J. INT'L DISP. SETTLEMENT 389, 392 (2010) (discussing responses).

2. Pauwelyn, *supra* note 1, at 395-96.

This Article argues that the availability of adjudication through the WTO has indeed had significant consequences for the policy space of developing countries—just not in the manner initially imagined. Although the TRIPS Agreement has given rise to relatively few litigated cases overall, the threat of defending a costly complaint and the possibility of sanctions have contributed to a culture of overcompliance that has discouraged countries from experimenting with flexibilities protected under the treaty.³ Yet the problem of trade adjudication is not so much a problem of *adjudication* as it is of *trade*. Although the decision to link trade and intellectual property has transformed intellectual property discourse in a variety of ways,⁴ one of its most underappreciated consequences has been the conflation of trade and intellectual property jurisprudence in TRIPS dispute resolution. In an important case interpreting exceptions and limitations under TRIPS, the panel applied an interpretive approach drawn from trade cases that was fundamentally at odds with the structure and purpose of the TRIPS Agreement. The decision to subject intellectual property decision making to adjudication within the trade system has thereby led to overly restrictive interpretations that do not respect the intentions of the parties or the needs of intellectual property policy making.

This Article proposes the use of a more deferential standard of review and a human rights presumption to remedy these overly restrictive interpretations. Panels should consider and respect the purposes states attempt to achieve through intellectual property regulation and should give greater presumptive weight to state policies that seek to fulfill human rights and protect human health and dignity. Additional deference to state priorities is appropriate given the object and purpose of the treaty and the nature of intellectual property regulation itself. Moreover, such deference is particularly important with respect to least developed countries. Several provisions of the WTO-covered agreements require special attention to the needs of least developed countries, and a deferential standard of review would be an important means of giving content to these terms.

Part I of this Article considers the possibility of overcompliance with the TRIPS Agreement, identifying the flexibilities protected under the treaty and discussing the way in which many states have refrained from implementing these flexibilities into domestic law. Part II examines how the

3. Cf. Graeme B. Dinwoodie, *The International Intellectual Property System: Treaties, Norms, National Courts, and Private Ordering*, in *INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT* 61, 77 (Daniel J. Gervais ed., 2007) (“International intellectual property law now has real teeth.”).

4. Some have condemned the “trade-IP” linkage as effectively establishing economics as the prime narrative for discussions about intellectual property, thus crowding out other important values and policy justifications (such as innovation) that might have provided a more balanced framework. Others have argued that the use of a trade framework allows the use of liability rather than property rules and thus opens up space for states to permit infringements when economically justified. See, e.g., Graeme B. Dinwoodie, *The Architecture of the International Intellectual Property System*, 77 CHI.-KENT L. REV. 993, 1004 (2002); Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 828 (2007).

decision to link intellectual property protection to the dispute resolution mechanism of the WTO has contributed to this reluctance to make use of TRIPS flexibilities. Part III argues for the adoption of a standard of review designed with intellectual property in mind, one that would consider the purposes a state regulation was designed to achieve and privilege human rights purposes. Part IV maintains that additional deference is especially warranted in reviewing the intellectual property policies of least developed nations.

I. TRIPS OVERCOMPLIANCE

With the negotiation of the TRIPS Agreement in 1994, developed countries successfully made compliance with certain minimum intellectual property standards a requirement of membership in the WTO. Under most definitions of the term, the TRIPS Agreement⁵ might be considered a success story for international law. Compared to most international treaties, the TRIPS Agreement has enjoyed not only widespread ratification but also high levels of domestic compliance—at least with respect to the laws on the books. In fact, one might even argue that it has been too successful. Despite considerable ambiguity in its terms and a professed commitment to imposing only minimum standards, states have not exploited these flexibilities to implement the treaty in ways consistent with local needs and values. Many have even adopted intellectual property laws that provide far greater protection than is required by the terms of the treaty itself.

A. TRIPS Flexibilities

One of the most widespread critiques of the TRIPS Agreement has been that it limits the ability of member states to tailor their domestic intellectual property laws in ways that foster innovation and protect human health and welfare.⁶ Peter Yu, for example, has characterized the TRIPS Agreement as

5. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement]. The TRIPS Agreement was negotiated as part of a set of agreements concluded in 1994 that created the WTO and strengthened the mechanism for resolving trade disputes. Annexed to the principal agreement establishing the WTO was a series of topic-specific agreements regulating issues ranging from trade in goods and services to textiles and clothing, agriculture, and antidumping (collectively called the “covered agreements”). The TRIPS Agreement is one of these covered agreements and establishes minimum standards for intellectual property protection in the domestic law of WTO member states. See generally *What Is the WTO?*, WORLD TRADE ORG. [WTO], http://www.wto.org/english/thewto_e/whatis_e/wto_dg_stat_e.htm (last visited Mar. 1, 2012).

6. See, e.g., Rochelle C. Dreyfuss, *TRIPS and Essential Medicines: Must One Size Fit All? Making the WTO Responsive to the Global Health Crisis*, in INCENTIVES FOR GLOBAL HEALTH 36, 52 (Thomas Pogge et al. eds., 2010); Anselm Kamperman Sanders, *Intellectual Property Treaties and Development*, in INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT, *supra* note 3, at 157, 164; James Boyle, *A Manifesto on WIPO and the Future of Intellectual Property*, 2004 DUKE L. & TECH. REV. 0009, at 3–4; Peter K. Yu, *The Objectives*

part of an “international enclosure movement” that has “enclose[d] the policy space of individual countries and require[d] them to adopt one-size-fits-all legal standards that ignore their local needs, national interests, technological capabilities, and public health conditions.”⁷

The ability to tailor intellectual property policies to domestic conditions is critical for several reasons. First, intellectual property policies may need to vary by country in order to protect human health and welfare. The debate about access to medicines is perhaps the best-known example of this: depending on its health needs and resources, a state may need to limit patent rights on some kinds of medicines in order to make those medicines affordable.⁸ The importance of tailoring intellectual property law to protect human rights extends to all types of intellectual property and all types of rights. Copyright may need to be limited through doctrinal tools such as fair use in order to ensure that educational materials do not become unaffordable or unavailable⁹ or to facilitate individuals’ ability to participate in culture.¹⁰ Fair use exceptions to copyright law help protect the right to free expression.¹¹ Patent rights may need to be limited in order to ensure the continued development of scientific research and the ability to share in the benefits of such research.¹² The kinds of human rights and public policy problems presented by intellectual property rights also vary by industry: “The broad patents available for basic science present different problems from those as-

and *Principles of the TRIPS Agreement*, 46 Hous. L. Rev. 979, 981 (2009); Henning Grosse Ruse-Khan, *IP Enforcement Beyond Exclusive Rights* 13 (Max Planck Inst. for Intellectual Prop., Competition & Tax Law, Research Paper Series No. 09-08, 2009).

7. Yu, *supra* note 4, at 828, 832 (emphasis omitted).

8. See Chuan-feng Wu, *Raising the Right to Health Concerns Within the Framework of International Intellectual Property Law*, 5 ASIAN J. WTO & INT’L HEALTH L. & POL’Y 141, 164–65 (2010).

9. See Margaret Chon, *Intellectual Property “from Below”: Copyright and Capability for Education*, 40 U.C. DAVIS L. REV. 803, 825–27 (2007).

10. See Molly Beutz Land, *Intellectual Property Rights and the Right to Participate in Cultural Life* 3–5 (Inst. for Info. Law & Policy at N.Y. Law Sch., White Paper Series 08/09 No. 02, 2009), available at <http://ssrn.com/abstract=1475430>.

11. See *Eldred v. Ashcroft*, 537 U.S. 186, 219 (2003) (noting that U.S. copyright law “contains built-in First Amendment accommodations” such as the idea-expression dichotomy and the fair use defense).

12. See Plaintiffs’ Memorandum of Law in Support of Motion for Summary Judgment at 37–38, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09-Civ-4515) (arguing that patents on certain genes violated Article I, Section 8, Clause 8 of the Constitution, which allows Congress to create exclusive rights “[t]o promote the Progress of Science and useful Arts,” because the patents impeded instead of promoted the progress of science). See generally Lea Shaver, *The Right to Science and Culture*, 2010 Wis. L. Rev. 121 (arguing that Article 27 of the Universal Declaration of Human Rights was intended to promote universal access to science and culture).

sociated with the thickets of narrow rights awarded in fields where advances are incremental.”¹³

Second, intellectual property policy must be tailored to local conditions in order to promote innovation and development. As Katherine Strandburg has noted, “it is particularly problematic to enshrine a one-size-fits-all approach to innovation in an international agreement because states are likely to be heterogeneous in their preferred innovation approaches.”¹⁴ The intellectual property policies that will foster innovation and development in one context are different from those necessary in another.¹⁵ For example, emerging economies like Brazil and India may benefit from robust intellectual property protection in certain areas.¹⁶ States may also need to vary across industries the strength of the protection they provide. China, for example, may want strong rights for its software industry but weaker rights for pharmaceuticals in order to ensure sufficient access to medicines and incentivize software production.¹⁷ Data exclusivity can provide incentives for research into traditional medicines in countries that have substantial indigenous-knowledge resources.¹⁸ The speed of changes in the digital environment has the potential to make flexibilities just as important for developed nations as they are for developing nations.¹⁹

Third, intellectual property policies must be tailored to conform to local values and concerns. Intellectual property policies often involve consideration of issues intimately bound up with local values, such as freedom of

13. Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement*, 13 MICH. TELECOMM. & TECH. L. REV. 445, 445 (2007).

14. Katherine J. Strandburg, *Evolving Innovation Paradigms and the Global Intellectual Property Regime*, 41 CONN. L. REV. 861, 891 (2009).

15. See Yu, *supra* note 4, at 896 (arguing that patent regulation must be tailored to each country’s individual “economic, social, cultural, and technological conditions”); see also Daniel J. Gervais, *TRIPS and Development*, in INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT, *supra* note 3, at 3, 51–52 (“[I]ntellectual property rules must be properly calibrated as part of a broader domestic innovation and knowledge optimization strategy.”); Henrique Choer Moraes & Otávio Brandelli, *The Development Agenda at WIPO: Context and Origins*, in THE DEVELOPMENT AGENDA 33, 42 (Neil Weinstock Netanel ed., 2009) (“In sum, numerous studies and leading development experts concur that countries must have flexibility to tailor IPR to their development needs.”); Neil Weinstock Netanel, *Introduction: The WIPO Development Agenda and Its Development Policy Context*, in THE DEVELOPMENT AGENDA, *supra*, at 1, 6 (“[I]t is apparent that the neoliberal one-size-fits-all approach to property and markets has no more purchase as it pertains to intellectual property than it does with respect to development generally.”).

16. Shamnad Basheer & Annalisa Primi, *The WIPO Development Agenda: Factoring in the “Technologically Proficient” Developing Countries*, in IMPLEMENTING THE WORLD INTELLECTUAL PROPERTY ORGANIZATION’S DEVELOPMENT AGENDA 100, 107 (Jeremy de Beer ed., 2009).

17. Peter K. Yu, *Intellectual Property, Economic Development, and the China Puzzle*, in INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT, *supra* note 3, at 173, 208–09.

18. Basheer & Primi, *supra* note 16, at 108.

19. Patricia L. Judd, *Toward a TRIPS Truce*, 32 MICH. J. INT’L L. 613, 642–43 (2011).

expression.²⁰ States may want broader exceptions to copyright for parody or news reporting in order to provide more protection to expression. States with indigenous populations may want more extensive protections for traditional knowledge. Others with artisanal or local production of specialty goods may want stronger protections for geographic indications.

Given the importance of tailored intellectual property policies, academics and activists have developed a variety of different proposals for increasing the policy space available to states to tailor innovation policy to local needs. Some have focused on halting the continual expansion of intellectual property norms through rules that would limit levels of international property protection²¹ or require exceptions and limitations to rights.²² Others have suggested limiting intellectual property rights through reliance on other sources of international obligations, such as human rights agreements,²³ or the development of norms that would require greater scrutiny when intellectual property rights conflict with basic needs.²⁴ An initiative headed by Annette Kur and Marianne Levin called “Intellectual Property Rights in Transition” has proposed several amendments to TRIPS that would expand the treaty’s “capacity to provide a balanced framework for legislative and adjudicative activities.”²⁵

Yet the critique that the TRIPS Agreement imposes “one-size-fits-all” solutions that must be limited through the creation of substantive ceilings, amendments to TRIPS, or external norms like human rights is in some ten-

20. See Graeme B. Dinwoodie, *A New Copyright Order: Why National Courts Should Create Global Norms*, 149 U. PA. L. REV. 469, 513–14 (2000).

21. See Annette Kur & Henning Grosse Ruse-Khan, *Enough Is Enough: The Notion of Binding Ceilings in International Intellectual Property Protection*, in INTELLECTUAL PROPERTY RIGHTS IN A FAIR WORLD TRADE SYSTEM 359, 360–66 (Annette Kur ed., 2011).

22. See P. BERNT HUGENHOLTZ & RUTH L. OKEDIJI, CONCEIVING AN INTERNATIONAL INSTRUMENT ON LIMITATIONS AND EXCEPTIONS TO COPYRIGHT 35–49 (2008), available at http://www.soros.org/initiatives/information/articles_publications/publications/copyright_20080506/copyright_20080506.pdf; Andrew Rens, *Implementing the WIPO Development Agenda: Treaty Provisions on Minimum Exceptions and Limitations for Education*, in IMPLEMENTING THE WORLD INTELLECTUAL PROPERTY ORGANIZATION’S DEVELOPMENT AGENDA, *supra* note 16, at 158, 158.

23. See, e.g., Christophe Geiger, *Implementing an International Instrument for Interpreting Copyright Limitations and Exceptions*, 40 INT’L REV. INTEL. PROP. & COMPETITION L. 627, 629–31 (2009); Ruth L. Okediji, *The Limits of Development Strategies at the Intersection of Intellectual Property and Human Rights*, in INTELLECTUAL PROPERTY, TRADE, AND DEVELOPMENT, *supra* note 3, at 355, 365. States and advocates have also used other norms and institutions to bring pressure on intellectual property law regimes. Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 1, 6 (2004) (calling this “regime shifting”).

24. Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2885 (2006).

25. ANNETTE KUR & MARIANNE LEVIN, THE IPT PROJECT: PROPOSALS TO REFORM THE TRIPS AGREEMENT 3 (2011), available at <http://infojustice.org/download/gcongress/limitationsandexceptionsforspecialsubjectsandobjects/Kur%20and%20Levin%20-%20%20Proposals%20to%20Reform%20the%20TRIPS%20Agreement%20-%20May%202011.pdf>.

sion with the goals and structure of the treaty itself. By its own terms, the TRIPS Agreement imposes only minimum standards. Although they are required to respect its provisions, WTO member states “may, but shall not be obliged to, implement in their law more extensive protection than is required” and “shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”²⁶ In recent years, scholars have begun to emphasize the way in which provisions of the TRIPS Agreement itself²⁷ or new ways of interpreting the treaty²⁸ provide significant flexibility to member states to limit the reach of intellectual property norms. Specifically, there are several different types of “flexibilities” contained in the Agreement that provide states with considerable leeway in implementing their obligations under the treaty.

Explicit exemptions. Certain kinds of regulatory decisions are explicitly reserved to states. For example, Article 27(2) allows countries to exclude inventions from patentability to “protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.”²⁹ The Agreement also provides countries with the authority to impose exceptions and limitations on exclusive rights³⁰ and expressly refrains from taking a position on the exhaustion of intellectual property rights, thus allowing countries to permit goods lawfully sold abroad to be imported into the country without requiring the right holder’s permission.³¹

26. TRIPS Agreement art. 1(1).

27. See Denis Borges Barbosa et al., *Slouching Towards Development in International Intellectual Property*, 2007 MICH. ST. L. REV. 71, 98–113; Yu, *supra* note 6, at 1020–31; Henning Grosse Ruse-Khan, *A Comparative Analysis of Policy Space in WTO Law* 62 (Max Planck Inst. for Intellectual Prop., Competition & Tax Law, Research Paper Series No. 08-02, 2008).

28. See Declaration on a Balanced Interpretation of the “Three-Step Test” in Copyright Law, reprinted in 39 INT’L REV. INTELL. PROP. & COMPETITION L. 707, 707–11 (2008); Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *Designing a Global Intellectual Property System Responsive to Change: The WTO, WIPO, and Beyond*, 46 HOUS. L. REV. 1187, 1215–16 (2009).

29. TRIPS Agreement art. 27(2). See generally Caroline Henckels, *The Ostensible “Flexibilities” in TRIPS: Can Essential Pharmaceuticals Be Excluded from Patentability in Public Health Crises?*, 32 MONASH U. L. REV. 335, 343–46 (2006) (discussing difficulties countries may encounter in taking advantage of Article 27(2)).

30. See TRIPS Agreement arts. 13, 17, 30. See generally SISULE F. MUSUNGU & CECILIA OH, COMM’N ON INTELL. PROP. RIGHTS, INNOVATION & PUB. HEALTH, *THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES?*, at iv–viii (2005) (discussing several explicit TRIPS flexibilities that could be used to promote access to medicines).

31. TRIPS Agreement art. 6. See generally CARLOS M. CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT* 78 (2007) (highlighting that Article 6 “declares the admissibility of the international exhaustion of rights, that is, the possibility of legally importing into a country a product protected by intellectual property rights, after the product has been put on the market in a foreign market”).

Balancing provisions. Two provisions of the Agreement, although not specifying particular limitations that states may impose on intellectual property rights, do identify general purposes that states may seek to achieve in implementing their obligations under the treaty. Article 7 provides:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.³²

Article 8 of the Agreement allows states to adopt measures consistent with the Agreement that are “necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development” or “to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”³³

Procedural flexibilities. Developing and least developed countries were given additional time to comply with the provisions of the Agreement. Developing countries had until January 1, 2000, to implement the Agreement³⁴ and could optionally delay application of the product patent provisions until January 1, 2005, in certain fields.³⁵ Least developed countries were given ten years to implement the treaty, or until January 1, 2005.³⁶ (This deadline has been extended to July 1, 2013, in general and until January 1, 2016, with respect to pharmaceuticals.)³⁷

Standards. Several provisions of the treaty establish what Yuval Shany calls “inherently flexible . . . ‘standard-type’ norms.”³⁸ The three most important of these are Articles 13, 17, and 30, which describe the conditions under which states may impose limitations or exceptions to copyright, trademark, and patent rights, respectively. These articles, which collectively govern “exceptions and limitations” to intellectual property, provide as follows:

32. TRIPS Agreement art. 7.

33. *Id.* art. 8(1)–(2).

34. *Id.* art. 65(1)–(3).

35. *Id.* art. 65(4).

36. *Id.* art. 66(1).

37. Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 for Least-Developed Country Members*, IP/C/40 (Nov. 30, 2005); Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, IP/C/25 (July 1, 2002).

38. Yuval Shany, *Toward a General Margin of Appreciation Doctrine in International Law?*, 16 EUR. J. INT’L L. 907, 914 (2005).

Article 13 [Copyright]: Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.

....

Article 17 [Trademark]: Members may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trademark and of third parties.

....

Article 30 [Patent]: Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.³⁹

The TRIPS Agreement does not define the terms “unreasonably,” “normal,” or “legitimate” as used in these articles, thus providing room for interpretation based on national conditions.

The Agreement also imposes standard-type norms in describing the obligations of states with respect to the enforcement of intellectual property rights. Article 41(1), for example, provides that members shall ensure that enforcement procedures “permit effective action” against acts of infringement and provides that they make available “expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.”⁴⁰ Article 41(1) does not, however, define “effective” or “expeditious,” leaving these terms to be interpreted consistently with local context.

Textual silence. Although it requires states to establish certain minimum levels of protection and to do so without discrimination, the treaty largely does not dictate the ways in which states should go about achieving these goals. For example, although states are required to ensure that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application,”⁴¹ the treaty does not define “new,” “inventive step,” or “industrial application.” India, for example, has taken advantage of this flexibility by excluding from patentability “both new uses of known substances and . . . new forms of known substances that do

39. TRIPS Agreement arts. 13, 17, 30.

40. *Id.* art. 41(1).

41. *Id.* art. 27(1).

not enhance 'efficacy.'"⁴² It has also established a high "inventive step" threshold for patents as well as "several innovative procedural mechanisms that could help examiners identify suspect patents and that could create hurdles for applicants."⁴³

B. Lack of Implementation

Despite the availability of a variety of flexibilities under the treaty, many countries have not taken advantage of these flexibilities to tailor national policies to local conditions. Carolyn Deere, in her survey of the implementation of the TRIPS Agreement, observes that a number of states—including many least developed countries—have explicitly forgone the flexibilities they would otherwise be entitled to use and have adopted national laws in excess of what is required by TRIPS.⁴⁴ Surprisingly, this variation does not seem to be a factor of economic development: some of the poorest countries had the highest levels of protection, while some developing countries with the greatest technological capacity had mixed approaches to implementation.⁴⁵

Granted, this process of "enclosure" has not been "unidirectional."⁴⁶ Developing countries and their allies have fought and won several legal and political battles to defend their rights to use TRIPS flexibilities in designing national intellectual property policies. South Africa successfully defended its right to issue compulsory licenses, thus preserving important bargaining power in pressuring pharmaceutical companies to reduce prices on antiretroviral medications.⁴⁷ The Declaration on the TRIPS Agreement and Public Health, signed during the Doha negotiations in 2001, recognized the ability of WTO members under the TRIPS Agreement to "tak[e] measures to protect public health."⁴⁸ Developing countries also organized around the

42. Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571, 1590 (2009); see also Dreyfuss, *supra* note 6, at 60 (noting several additional ways in which India could revise its law to limit patentability in ways consistent with TRIPS).

43. Kapczynski, *supra* note 42, at 1598.

44. See, e.g., CAROLYN DEERE, *THE IMPLEMENTATION GAME* 73, 81, 91–94, 98 (2009) (describing instances where countries implemented the TRIPS Agreement in excess of required standards).

45. *Id.* at 102. A number of states have also entered into bilateral trade and investment agreements in which they have bound themselves to provide "TRIPS-plus" protection beyond that required by the TRIPS Agreement to nationals of the other contracting state. *Id.* at 151–55.

46. Yu, *supra* note 4, at 872.

47. See generally Robert Weissman, *AIDS Drugs for Africa: Grassroots Pressure Overcomes U.S.-Industry "Full Court Press" to Block South Africa's Affordable Medicine Program*, MULTINAT'L MONITOR, Sept. 1999, at 9, available at <http://www.multinationalmonitor.org/mmm1999/091999/weissman.html>.

48. WTO, Ministerial Declaration of 20 November 2001 on the TRIPS Agreement and Public Health, ¶ 4, WT/MIN(01)/DEC/2 (2001) [hereinafter Declaration on the TRIPS Agreement and Public Health].

Development Agenda, a set of principles adopted by the World Intellectual Property Organization (WIPO) that “reflects developing countries’ growing resistance to the upward harmonization of IP protection required by the TRIPS and subsequent ‘TRIPS-plus’ bilateral free trade agreements.”⁴⁹

Furthermore, some states have taken advantage of the flexibilities allowed under the TRIPS Agreement. As Deere documents, thirty-three developing countries have adopted a rule of international exhaustion, which exhausts the right holder’s ability to object to further distribution or importation of that particular good once the good is sold anywhere in the world.⁵⁰ All of the developing countries Deere surveyed that had updated their intellectual property laws to conform with TRIPS excluded diagnostic, therapeutic, and surgical methods from patentability.⁵¹ A majority allowed third parties to use inventions under patent for experimental, scientific, or research purposes.⁵² Most also allowed compulsory licensing of patented inventions, although the grounds for issuing such licenses varied.⁵³

India has been particularly innovative in redesigning its intellectual property policies in ways that increase access to medicines. As Amy Kapczynski has described, India implemented several new and innovative flexibilities when it revised its laws to comply with the TRIPS Agreement, including “novel limitations on subject matter, an exceptionally high inventive step standard, procedural requirements that could substantially decrease the grant rate, a patent misuse standard that may sharply constrain voluntary licensing activity, and perhaps most strikingly, limits on injunctive remedies.”⁵⁴ Among other things, these legal innovations would limit patents on new uses for known substances that do not enhance efficacy, thus preventing companies from obtaining successive patents (and thus an extended term of protection) on changes to a pharmaceutical not related to the drug’s efficacy.⁵⁵ India’s laws would also require the disclosure of additional information during the patent application process, a requirement that “can both increase the accuracy of determinations in the patent office and decrease the grant rate.”⁵⁶ Finally, the use of damages instead of injunctive relief could encourage generic companies to “enter the market and invite

49. Netanel, *supra* note 15, at 2–3; *see also* Ruth L. Okediji, *History Lessons for the WIPO Development Agenda*, in *THE DEVELOPMENT AGENDA*, *supra* note 15, at 137, 140.

50. DEERE, *supra* note 44, at 75–76. Because the sale of the IP-protected good anywhere in the world exhausts the right holder’s rights with respect to that good, a rule of international exhaustion enables parallel importation, which is the importation of “IP-protected products (such as patented medicines) from countries where they may be sold at a lower price than on the domestic market.” *Id.* at 75.

51. *Id.* at 77.

52. *Id.* at 81.

53. *Id.* at 81–82.

54. Kapczynski, *supra* note 42, at 1589.

55. *Id.* at 1590–91.

56. *Id.* at 1601.

infringement suits or licenses wherever they could markedly undercut the originator's price."⁵⁷

Despite these successes, efforts to use TRIPS flexibilities have been remarkably limited overall. In the area of patents, only the Andean Community (a subregional union comprising Bolivia, Colombia, Ecuador, and Peru)⁵⁸ and five other countries have excluded all plant, animal, and genetic material from patentability.⁵⁹ The TRIPS Agreement is silent on whether states must grant patents on new uses for known substances, but only twelve of 106 developing countries surveyed in 2006 specifically excluded these from patentability.⁶⁰ Fewer than ten of these surveyed countries allowed use of patented goods in order to obtain marketing approval.⁶¹ Most also had fairly rigorous protection for test data, even though TRIPS provides considerable flexibility in this regard. As Deere notes, although TRIPS allows countries to decide "whether information provided to a pharmaceutical regulatory authority can be relied on by a subsequent applicant seeking to obtain approval for a bio-equivalent product," according to a survey of forty-nine developing countries, only Argentina explicitly allowed subsequent applicants to rely on such data; in forty-one others, this ability was curtailed, and in ten, it was prohibited or severely curtailed.⁶²

There has been even less use of flexibilities with respect to copyrights. The TRIPS Agreement is compatible with a range of exceptions and limitations to copyright that could significantly increase access to information, education, and culture. For example, copyright can be limited in order to allow personal use, criticism and review, educational use, reproduction by the press, recording of broadcasts for the creation of official archives, and reproductions by libraries.⁶³ Countries can also limit copyright to increase access to creative works by people with disabilities or to facilitate interoperability of computer programs.⁶⁴ Yet few countries have made broad use of these copyright exceptions and limitations. As Deere notes, "[t]he majority of developing countries provided only a limited range of limitations and exceptions to copyright" and "made little use of TRIPS flexibilities that might have helped improve access to education and distance learning."⁶⁵ Some did provide individual exceptions for education, science, and translation,⁶⁶ among other things, but few have followed the lead of developed countries

57. *Id.* at 1607.

58. *About Us*, COMUNIDAD ANDINA, <http://www.comunidadandina.org/ingles/who.htm> (last visited Mar. 1, 2012).

59. DEERE, *supra* note 44, at 77–78.

60. *Id.* at 78–79.

61. *Id.* at 81.

62. *Id.* at 84.

63. *Id.* at 90.

64. *Id.*

65. *Id.* at 91.

66. *Id.* at 91–92.

such as the United States, Canada, and the United Kingdom in enacting a broad exclusion for “fair use.”⁶⁷ In addition, a significant number of countries have adopted terms of protection that far exceed the required term of the life of the author plus fifty years.⁶⁸

II. LINKING IP TO WTO DISPUTE RESOLUTION

Although the feared explosion of TRIPS litigation against developing countries never materialized, the threat of such litigation has contributed to a culture of overcompliance. Further, the pressures on states to implement provisions in excess of what is required by the treaty have been compounded by overly restrictive interpretations that bar consideration of public policy. This Part discusses the way in which the decision to subject the TRIPS Agreement to trade dispute resolution has restricted the policy space available to states to tailor their national intellectual property policies.

A. Threat of Litigation

The decision to subject the TRIPS Agreement to the dispute resolution mechanism of the WTO was highly contested at the time of the treaty’s conclusion. Developed countries negotiating the TRIPS Agreement insisted that intellectual property be subject to the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU).⁶⁹ The DSU provides a mechanism for states to bring complaints against one another for violations of any WTO agreement and to obtain a binding decision on that complaint from an adjudicatory panel.⁷⁰ The DSU also establishes a standing body, called the Appellate Body, that hears appeals of panel decisions.⁷¹ A panel can sanction a member state for violating the TRIPS Agreement by authorizing the complaining state to suspend trade benefits to which the violator state is otherwise entitled by virtue of its membership in the WTO.⁷² If the violator state does not comply with a panel’s recommendations,⁷³ the DSU allows the complaining state to “request authorization . . . to suspend the

67. *Id.* at 91.

68. *Id.* at 92–93.

69. Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU].

70. *Id.* arts. 4, 16(4).

71. *Id.* art. 17.

72. *Id.* art. 22(1). Compensation is also available but is “voluntary,” *id.*, and thus “depends on a common agreement between the parties to the dispute,” TRIPS RESOURCE BOOK, *supra* note 1, at 688.

73. See DSU art. 19 (“Where a panel or the Appellate Body concludes that a measure is inconsistent with a covered agreement, it shall recommend that the Member concerned bring the measure into conformity with that agreement.”).

application to the Member concerned of concessions or other obligations under the covered agreements.”⁷⁴

Several developing nations initially opposed applying the DSU to the TRIPS Agreement, fearing that it would result in significant litigation against developing countries.⁷⁵ At the same time, there were also potential benefits. Developing countries hoped that the DSU’s prohibition on unilateral trade retaliation could restrain the risk of unilateral trade sanctions.⁷⁶ They also hoped that “legalization”⁷⁷ of dispute resolution at the WTO would help “insulat[e] them against the pressures of power politics” and “limit the scope of the debate to the legal merits.”⁷⁸ In the end, proponents of dispute resolution prevailed. Article 64 of the TRIPS Agreement provides that disputes under that Agreement will be resolved pursuant to the dispute resolution mechanism of the DSU.⁷⁹

Although the decision to subject the TRIPS Agreement to the WTO dispute resolution mechanism did not result in the explosion of litigation that many had feared,⁸⁰ it nonetheless has been a factor in limiting the space available for developing country experimentation. As Carolyn Deere has documented, developed countries used the DSU process together with threats of unilateral economic sanctions to pressure countries to forgo flexibilities.⁸¹ Of course, the threat of litigation was only one of many factors driving implementation. Other factors that influenced the ways in which implementation occurred included domestic capacity for

74. *Id.* art. 22(2). Sanctions are generally limited to the sector in which the violation occurred but may be expanded to other sectors or other covered agreements if necessary. *Id.* art. 22(3)(a)–(c). The level of the sanction imposed must be equal to the harm occurring as a result of the violation, *id.* art. 22(4), and the Dispute Settlement Body must refer disputes about the sanction to arbitration in certain circumstances, *id.* art. 22(6).

75. TRIPS RESOURCE BOOK, *supra* note 1, at 659–64; Pauwelyn, *supra* note 1, at 392.

76. See TRIPS RESOURCE BOOK, *supra* note 1, at 663, 686; Karen Kaiser, *Article 64: Dispute Settlement*, in *WTO: TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS* 798, 800 (Peter-Tobias Stoll et al. eds., 2009).

77. The reforms of the dispute settlement process associated with the creation of the WTO have been characterized as a process of “legalization.” See, e.g., Gregory Shaffer, *How to Make the WTO Dispute Settlement System Work for Developing Countries: Some Proactive Developing Country Strategies*, in *TOWARDS A DEVELOPMENT-SUPPORTIVE DISPUTE SETTLEMENT SYSTEM IN THE WTO* 1, 9 (Victor Mosoti ed., 2003).

78. Hansel T. Pham, *Developing Countries and the WTO: The Need for More Mediation in the DSU*, 9 HARV. NEGOT. L. REV. 331, 347 (2004).

79. The DSU applies to the TRIPS Agreement with one limited exception—the treaty temporarily exempts from the dispute resolution procedures complaints directed at actions that deprive another state of the benefits of the TRIPS Agreement while adhering to WTO obligations, called non-violation complaints. TRIPS Agreement art. 64; see TRIPS RESOURCE BOOK, *supra* note 1, at 664, 669 (discussing the difference between violation and non-violation complaints).

80. Pauwelyn, *supra* note 1, at 395 (noting that “the flood of IP disputes expected by some did not materialize”).

81. See DEERE, *supra* note 44, at 156–58.

intellectual property policy making,⁸² external pressure such as media campaigns and technical assistance,⁸³ unilateral economic pressure,⁸⁴ and public engagement.⁸⁵ Nor does the availability of litigation explain decisions to forgo transitional periods and implement the treaty ahead of schedule.⁸⁶ At the same time, even those countries that had little reason to fear WTO litigation experienced pressure from developed countries because strong intellectual property laws in smaller states isolated “the larger, more competitive and less-malleable developing countries” and made it easier to marshal support for “TRIPS-plus” agreements.⁸⁷

Although it may not be possible to identify specific actions forgone by developing countries because of the threat of a WTO complaint,⁸⁸ the possibility of litigation appears to have contributed to an overall culture of TRIPS compliance. The United States, for example, saw its WTO complaint against Brazil as a “‘warning shot’ . . . to the developing countries that had hopes of using the flexibilities provided by the TRIPS Agreement.”⁸⁹ As Deere explains, “Even for countries not directly subjected to them, economic pressures reinforced an international policy climate in which it was clear that taking steps toward stronger IP protection would be favoured by powerful donors, foreign companies, and trading partners.”⁹⁰ In this way, the threat of litigation and the possibility of WTO-authorized trade sanctions played a critical role in creating a “pro-IP political climate for IP reforms.”⁹¹

82. See, e.g., *id.* at 197–232; Jerome H. Reichman, *Intellectual Property in the Twenty-First Century: Will the Developing Countries Lead or Follow?*, 46 Hous. L. Rev. 1115, 1165–67 (2009); Yu, *supra* note 17, at 197.

83. See DEERE, *supra* note 44, at 167–86; Kapczynski, *supra* note 42, at 1574 (noting that ratification of the TRIPS Agreement “inserts countries into a transnational circuit that fills in the gaps in the Agreement and that works against the use of TRIPS flexibilities”). See generally ABRAM CHAYES & ANTONIA HANDLER CHAYES, *THE NEW SOVEREIGNTY* (1995) (arguing that treaty compliance depends on managerial processes such as reporting, monitoring, and capacity building).

84. DEERE, *supra* note 44, at 151–55, 159–64, 306.

85. *Id.* at 312–13.

86. I am grateful to Joel Trachtman for this point. See also DEERE, *supra* note 44, at 306 (noting that some states that had never been “cited on the U.S. Special 301 list or subject to a WTO dispute” enacted some of the strongest intellectual property laws).

87. DEERE, *supra* note 44, at 116.

88. Given how few intellectual property cases have been brought to the WTO, such analysis may also be premature. Cf. Steve Charnovitz, *Rethinking WTO Trade Sanctions*, 95 AM. J. INT’L L. 792, 809 (2001) (arguing that “it is too soon to judge the efficacy of WTO trade sanctions in inducing compliance” and that “the efficacy of sanctions should not be a deciding factor in appraising the trade sanction tool”).

89. Sangeeta Shashikant, *The Doha Declaration on TRIPS and Public Health: An Impetus for Access to Medicines*, in ACCESS TO KNOWLEDGE IN THE AGE OF INTELLECTUAL PROPERTY 141, 144 (Gaëlle Krikorian & Amy Kapczynski eds., 2010).

90. DEERE, *supra* note 44, at 306.

91. See *id.* at 156–59.

This “pro-IP” climate was exacerbated by the polarized rhetoric used by proponents and opponents of strengthened intellectual property protections worldwide. As Joost Pauwelyn argues, the perception of TRIPS as bad for developing countries was in large part a result of spin by the intellectual property lobby: “Upon the conclusion of TRIPS, IP industries touted the agreement as a big victory that would widen and deepen worldwide IP protection with little or no flexibility including for developing countries once TRIPS entered into force for those countries on 1 January 2000.”⁹² This refrain was taken up by many of the intellectual property skeptics, who, in pushing back against the TRIPS Agreement, emphasized the perceived inflexibility of TRIPS and the way in which it limited the ability of developing countries to respond to domestic health crises.⁹³

Further, there is reason to think that developing and least developed countries might be particularly sensitive to the threat of litigation. As Deere notes, “[f]or trade-dependent, IP-importing developing countries, the prospect that failure to implement TRIPS could result in trade retaliation is one of the Agreement’s most pernicious aspects.”⁹⁴ Trade sanctions that result in the withdrawal of concessions essential for domestic industries may be especially difficult for developing countries to bear.⁹⁵ Developing nations also may have access to less domestic legal expertise in the area of intellectual property and fewer resources to initiate or defend against suits.⁹⁶ Because they are less likely to be repeat players, developing nations also “benefit from fewer economies of scale in deploying legal resources.”⁹⁷ They also tend to encounter greater barriers in bringing disputes before the WTO, largely stemming from the complexity of the system and procedures.⁹⁸

92. Pauwelyn, *supra* note 1, at 425. This rhetoric was in tension with efforts to obtain bilateral “TRIPS-plus” treaties that imposed higher standards than those of the TRIPS Agreement. As Deere notes, developed countries felt that the TRIPS Agreement was not strong enough and that additional measures were needed to ensure that developing nations implemented strong intellectual property norms and did not make use of TRIPS flexibilities. DEERE, *supra* note 44, at 113–14.

93. See Pauwelyn, *supra* note 1, at 425–26.

94. DEERE, *supra* note 44, at 65.

95. TRIPS RESOURCE BOOK, *supra* note 1, at 682.

96. Gregory Shaffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides?*, 7 J. INT’L ECON. L. 459, 472 (2004) (citing “the relatively high cost of access to the system and developing countries’ reduced economies of scale for mobilizing legal resources”); *id.* at 475 (noting the “small supply of lawyers educated in WTO law within developing countries”); *cf.* Dinwoodie, *supra* note 20, at 509.

97. Shaffer, *supra* note 96, at 474.

98. Frieder Roessler, *Special and Differential Treatment of Developing Countries Under the WTO Dispute Settlement System*, in THE WTO DISPUTE SETTLEMENT SYSTEM 1995–2003, at 87, 88 (Federico Ortino & Ernst-Ulrich Petersmann eds., 2004) (quoting Marc L. Busch & Eric Reinhardt, *Testing International Trade Law: Empirical Studies of GATT/WTO Dispute Settlement*, Paper Presented at the Conference on the Political Economy of International Trade Law at the University of Minnesota Law School (Sept. 15–16, 2000)).

In some respects, the caution of developing countries in applying mandatory dispute resolution to the TRIPS Agreement appears to have been unwarranted. Joost Pauwelyn explains that relatively few of the disputes handled under the DSU have involved violations of the TRIPS Agreement, and the number of such cases appears to be declining.⁹⁹ Even fewer have involved developing countries, and in none of these cases have sanctions been imposed against developing countries.¹⁰⁰ Yet the lack of litigation may in fact have exacerbated the pressures on states to forgo flexibilities, since the absence of normative content with respect to many provisions of the TRIPS Agreement increases the risk involved in testing the boundaries of the treaty.¹⁰¹ This is particularly true for developing countries. The lack of cases against developing countries means that “there has been no opportunity to generate the norms that would provide developing countries with guidance on what sorts of moves they can safely regard as compatible with international obligations.”¹⁰² Finally, the fact that most TRIPS complaints have been addressed to challenging a legal provision in domestic law instead of its application to a particular context has heightened their signaling capacity: “It goes without saying that when such systemic complaints are won, a strong warning signal is sent to the entire WTO membership”¹⁰³

Further, the protection that developing countries hoped the DSU would provide against unilateral economic pressure did not materialize.¹⁰⁴ The WTO dispute settlement procedures were introduced in part to provide greater oversight of and to limit the use of potentially opportunistic and excessive unilateral retaliation.¹⁰⁵ Replacing unilateral with multilateral sanctions would theoretically reduce the perceived risks associated with litigation,¹⁰⁶ and developing countries had indeed hoped for less unilateral pressure from the United States.¹⁰⁷ The United States, however, has continued

99. Pauwelyn, *supra* note 1, at 395–96; see Yoshifumi Fukunaga, *Enforcing TRIPS: Challenges of Adjudicating Minimum Standards Agreements*, 23 BERKELEY TECH. L.J. 867, 884–87 (2008).

100. Pauwelyn, *supra* note 1, at 395, 418. At the same time, sanctions are only one method—and not necessarily the most effective method—of enforcing compliance with international treaties. *E.g.*, CHAYES & CHAYES, *supra* note 83, at 33.

101. Dinwoodie & Dreyfuss, *supra* note 28, at 1214; Reichman, *supra* note 82, at 1132 (noting that “the risk of endless litigation over uncertain legal boundaries leads to daunting litigation costs”).

102. See Rochelle C. Dreyfuss, *The Role of India, China, Brazil and Other Emerging Economies in Establishing Access Norms for Intellectual Property and Intellectual Property Lawmaking 7* (N.Y. Univ. Sch. of Law Pub. Law & Legal Theory Res. Paper Series, Working Paper No. 09-53, 2009).

103. Pauwelyn, *supra* note 1, at 400.

104. See DEERE, *supra* note 44, at 159.

105. Warren F. Schwartz & Alan O. Sykes, *The Economic Structure of Renegotiation and Dispute Resolution in the World Trade Organization*, 31 J. LEGAL STUD. S179, S202 (2002).

106. TRIPS RESOURCE BOOK, *supra* note 1, at 686.

107. Kaiser, *supra* note 76, at 800.

to employ its Special 301 process¹⁰⁸ and has successfully defended a challenge to the process as incompatible with TRIPS, although the impact of this threat has been limited by the United States' position in that litigation that it would not use this process in ways inconsistent with TRIPS.¹⁰⁹

B. *The Incoherence of TRIPS Jurisprudence*

By itself, concern about the threat of WTO dispute resolution might be viewed as simply an ordinary consequence of the parties' bargain. Mandatory dispute resolution is in fact *intended* to constrain the options available to states and to encourage them to make changes in their domestic law consistent with TRIPS. It was not, however, intended to constrain these options entirely. Developing countries insisted on the inclusion of provisions in the TRIPS Agreement to protect the policy space needed to tailor their laws to national priorities. Yet WTO dispute resolution panels have interpreted these provisions in ways that significantly restrict states' willingness and ability to take advantage of these flexibilities.¹¹⁰ In part, this may be a function of overly legalistic reasoning in trade disputes generally.¹¹¹ In the context of intellectual property, however, it is also a result of a mismatch between trade dispute reso-

108. Donald Harris, *TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. INTELL. PROP. L. 367, 373 (2011) (noting that the United States has continued to use the 301 process despite the hopes of some developing countries that "TRIPS would shield them from further United States unilateral action").

109. See Panel Report, *United States—Sections 301–310 of the Trade Act of 1974*, ¶¶ 7.125–7.126, 7.131, 7.135, WT/DS152/R (Dec. 22, 1999) (finding that, although Section 304 constituted a prima facie violation of Article 23.2(a), the United States had expressed an "unambiguous and official position" that prevented it "from making a determination of inconsistency contrary to Article 23.2(a)," thus rendering Section 304 consistent with the DSU).

110. Duncan Matthews notes, for example, that "there were doubts about whether Article 30 [of] TRIPS could in fact be used as a limited exception for the exportation of medicines to non-producing developing countries," not only because of "strong opposition from the United States and the research-based pharmaceutical industry," but also because "[t]he *EC-Canada* WTO Dispute Settlement Panel had . . . created uncertainties by stressing the limited nature of exceptions to exclusive rights conferred by a patent under Article 30." DUNCAN MATTHEWS, *INTELLECTUAL PROPERTY, HUMAN RIGHTS AND DEVELOPMENT: THE ROLE OF NGOS AND SOCIAL MOVEMENTS* 40–41 (2011) (citation omitted); see also Shaffer, *supra* note 96, at 471 (noting that states operate in the "shadow" of the law, and the "WTO law's substance, as defined through WTO jurisprudence, provides bargaining chips, informing and constraining settlement negotiations").

111. See, e.g., Henrik Horn & Petros C. Mavroidis, *International Trade: Dispute Settlement*, in RESEARCH HANDBOOK IN INTERNATIONAL ECONOMIC LAW 177, 208 (Andrew T. Guzman & Alan O. Sykes eds., 2007) ("[WTO] decisions are extremely deferential to the words used in the WTO agreement, which are often read in clinical isolation from their context, that is, without WTO judges asking, and answering, the question of what function any given legal instrument has been assigned to play"); Dispute Settlement Body, *Negotiations on the Dispute Settlement Understanding: Proposal by the LDC Group*, ¶ 5, TN/DS/W/17 (Oct. 9, 2002) (reflecting concern that "[t]he panels and the Appellate Body have displayed an excessively sanitized concern with legalisms, often to the detriment of the evolution of a development-friendly jurisprudence").

lution and intellectual property balancing. Situating intellectual property disputes within a trade dispute resolution mechanism has led to jurisprudence that is both internally incoherent and inconsistent with the goals of intellectual property balancing and the proper interpretation of the TRIPS Agreement.

Several provisions in the text of the TRIPS Agreement were designed to afford deference to national priorities in creating intellectual property policies. For example, Article 13 of the TRIPS Agreement allows states to limit copyright rights as long as the exception is confined to “certain special cases” and does not “unreasonably prejudice” the rights of the intellectual property owner.¹¹² Articles 17 and 30 contain similar terms (e.g., “legitimate interests,” “unreasonably conflict,” and “unreasonably prejudice”).¹¹³ In the area of enforcement, Article 41 requires parties to ensure that enforcement procedures “permit effective action.”¹¹⁴ Each of these terms would, on its face, appear to require consideration of local conditions and the policy goals the state sought to achieve through the exception. For example, the term “special” would seem to call for an evaluation of whether the case is unique or different in terms of, among other things, the purposes it is designed to serve. A case is “special” if it is different from others, including with reference to its objective or rationale. “Unreasonable” would appear to require a comparison of the prejudice imposed on rights holders with the public policy goals the state sought to achieve with the limitation. What might constitute “unreasonable prejudice” under Article 13 in one context could well be reasonable in another given important countervailing public policy goals.

WTO panels, however, have nearly read these standard-type norms out of the Agreement. In interpreting Article 13, for example, a WTO panel adopted an interpretation of “special” that disregarded any consideration of context. In *U.S.—Section 110(5) Copyright Act*, the European Communities challenged two provisions of U.S. law as violations of the TRIPS Agreement.¹¹⁵ Among other things, the United States argued that the challenged exceptions conformed to Article 13, which allowed limitations and exceptions to rights provided they met the three-step test described above.¹¹⁶ Relying on the *Oxford English Dictionary*, the panel rejected the United States’ argument that the purpose of the exception should be considered in determining whether a case is “special” enough to warrant an exception.¹¹⁷ The panel defined the term “special” as requiring only that the exception “be

112. TRIPS Agreement art. 13. This is called the “three-step” test. *See, e.g.,* CORREA, *supra* note 31, at 146.

113. TRIPS Agreement arts. 17, 30.

114. *Id.* art. 41.

115. Panel Report, *United States—Section 110(5) of the US Copyright Act*, WT/DS160/R (June 15, 2000) [hereinafter *U.S.—Section 110(5) Copyright Act*].

116. First Written Submission of the United States, *U.S.—Section 110(5) Copyright Act*, *supra* note 115, Attachment 2.1.

117. *U.S.—Section 110(5) Copyright Act*, *supra* note 115, ¶ 6.111.

narrow in its scope and reach.”¹¹⁸ Although the panel noted that “public policy purposes stated by law-makers when enacting a limitation or exception may be useful,” this was only to the extent such purposes would allow “inferences about the *scope* of a limitation or exception.”¹¹⁹ Similarly, in defining “unreasonable prejudice,” the panel considered primarily the amount of economic harm to the rights owner and disregarded the purpose served by the exception.¹²⁰ Thus, both “special” and “unreasonable” were defined by the panel in ways that require consideration only of whether the exception crosses some undefined economic threshold, not whether it was appropriate in the local context.¹²¹

One of the reasons the *U.S.—Section 110(5) Copyright Act* panel adopted such a restrictive interpretation of the TRIPS Agreement was its reliance on jurisprudence from trade cases to interpret Article 13.¹²² Although there is technically no concept of “precedent” within the WTO system, “in practical terms, prior decisions are not lightly departed from.”¹²³ Typically, this

118. *Id.* ¶ 6.112.

119. *Id.* (emphasis added). In other cases, however, panels have explicitly recognized that

dictionaries are a “useful starting point” for the analysis of “ordinary meaning” of a treaty term, but they are not necessarily dispositive. The ordinary meaning of a treaty term must be ascertained according to the particular circumstances of each case. Importantly, the ordinary meaning of a treaty term must be seen in the light of the intention of the parties “as expressed in the words used by them against the light of the surrounding circumstances.”

Panel Report, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, ¶ 7.559, WT/DS362/R (Jan. 26, 2009) [hereinafter *China—Intellectual Property Rights*] (citing Appellate Body Report, *European Communities—Customs Classification of Frozen Boneless Chicken Cuts*, ¶ 175, WT/DS269/AB/R, WT/DS286/AB/R (Sept. 12, 2005) [hereinafter *EC—Chicken Cuts*]).

120. *U.S.—Section 110(5) Copyright Act*, *supra* note 115, ¶ 6.271.

121. See, e.g., Annette Kur, *Limitations and Exceptions Under the Three-Step Test—How Much Room to Walk the Middle Ground?*, in *INTELLECTUAL PROPERTY RIGHTS IN A FAIR WORLD TRADE SYSTEM*, *supra* note 21, at 208, 236 (“[W]ith the exception of the trademark report, nowhere do the panels venture into a discussion of the policies underlying the limitations at stake.”); Dinwoodie & Dreyfuss, *supra* note 28, at 1207 (characterizing the adjudicators in TRIPS cases as doing “little more than mechanically count[ing] the number of rights within the bundle affected by the challenged provision, or the number of situations in which the exception was applicable”).

122. There may be, of course, several other reasons why panels have interpreted the three-step test so narrowly. Rochelle Dreyfuss observes, for example, that most disputes have involved developed countries, none of which have an incentive to argue for maximal flexibility in the terms of the TRIPS Agreement. Dreyfuss, *supra* note 102, at 14–15. Annette Kur considers and rejects the argument that panels disregard context in order to “preserve the evaluation of policy aspects to a later stage,” arguing that this is “highly questionable if an exception is already ‘sorted out’ with the first step, and therefore never reaches a stage where policy considerations are included in the assessment.” Kur, *supra* note 121, at 227.

123. Michael Lennard, *Navigating by the Stars: Interpreting the WTO Agreement*, 5 J. INT’L ECON. L. 17, 33 (2002). Panel decisions are not considered “subsequent practice” under

reliance on prior decisions is not problematic. Panels adjudicating TRIPS disputes often rely on decisions interpreting other covered agreements to establish general principles of treaty interpretation,¹²⁴ to interpret similar terms in similar ways,¹²⁵ or to identify general procedural approaches.¹²⁶ For example, in *EC—Trademarks and Geographical Indications*, the panel interpreted the phrase “no less favourable” in the TRIPS Agreement consistently with the same phrase in Article III of the General Agreement on Tariffs and Trade (GATT).¹²⁷ Relying on decisions interpreting similar language in other covered agreements is also consistent with Article 31(2)(a) of the Vienna Convention on the Law of Treaties (VCLT), which allows consideration of an “agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty.”¹²⁸

Although reliance on prior decisions is unproblematic in many situations, the panel in *U.S.—Section 110(5) Copyright Act* should not have used trade cases to interpret Article 13 because of fundamental differences between the TRIPS Agreement and other WTO-covered agreements in their

the Vienna Convention on the Law of Treaties. Appellate Body Report, *Japan—Taxes on Alcoholic Beverages* 13–14, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (Oct. 4, 1996) [hereinafter *Japan—Alcoholic Beverages II*].

124. Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 46, WT/DS50/AB/R (Dec. 19, 1997); Panel Report, *European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, ¶ 7.208, WT/DS174/R (Mar. 15, 2005) [hereinafter *EC—Trademarks and Geographical Indications*]; *China—Intellectual Property Rights*, *supra* note 119, ¶ 7.559.

125. Panel Report, *European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, ¶ 7.183, WT/DS290/R (Mar. 15, 2005). See generally Susy Frankel, *The Applicability of GATT Jurisprudence to the Interpretation of the TRIPS Agreement*, in RESEARCH HANDBOOK ON THE INTERPRETATION AND ENFORCEMENT OF INTELLECTUAL PROPERTY UNDER WTO RULES 3, 11–14 (Carlos M. Correa ed., 2010) (citing General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT]) (detailing the use of GATT provisions to interpret national treatment and most-favored-nation provisions in TRIPS). Frankel, for example, has argued that GATT jurisprudence is “relevant to the way in which concepts such as ‘human, animal or plant life or health’ should be interpreted.” *Id.* at 22.

126. *China—Intellectual Property Rights*, *supra* note 119, ¶ 7.141.

127. *EC—Trademarks and Geographical Indications*, *supra* note 124, ¶ 7.133. The panel also stated:

The interpretation of the “no less favourable” treatment standard under other covered agreements may be relevant in interpreting Article 3.1 of the TRIPS Agreement, taking account of its context in each agreement including, in particular, any differences arising from its application to like products or like services and service suppliers, rather than to nationals.

Id. ¶ 7.135.

128. Vienna Convention on the Law of Treaties art. 31, May 23, 1969, 1155 U.N.T.S. 331 [hereinafter VCLT]; see Panel Report, *United States—Transitional Safeguard Measure on Combed Cotton Yarn from Pakistan*, ¶ 7.46, WT/DS192/R (May 31, 2001) (noting, in interpreting the Agreement on Textiles and Clothing, that “it is the WTO Agreement in its entirety, including GATT Article III, that provides the context of Article 6 of the ATC”).

approaches to national tailoring. Specifically, the panel in that case relied on decisions of prior panels interpreting GATT and the General Agreement on Trade in Services (GATS). The critical provision of the *U.S.—Section 110(5) Copyright Act* decision states as follows:

As regards the parties' arguments on whether the public policy purpose of an exception is relevant, we believe that the term "certain special cases" should not lightly be equated with "special purpose." It is difficult to reconcile the wording of Article 13 with the proposition that an exception or limitation must be justified in terms of a legitimate public policy purpose in order to fulfill the first condition of the Article. We also recall in this respect that *in interpreting other WTO rules, such as the national treatment clauses of the GATT and the GATS*, the Appellate Body has rejected interpretative tests which were based on the subjective aim or objective pursued by national legislation.¹²⁹

In this paragraph, the panel cites to cases interpreting GATT and GATS, including the Appellate Body's decisions in *Japan—Alcoholic Beverages II* and *EC—Bananas III*.¹³⁰ In those cases, the Appellate Body rejected the use of the "aims and effects" test in interpreting state obligations under GATT.¹³¹ Article III(1) of GATT prohibits discriminating against foreign products "so as to afford protection" to domestic products.¹³² States had initially argued that this meant that a discriminatory measure could only be struck down if "a change in competitive opportunities in favour of domestic products was a desired outcome and not merely an incidental consequence of the pursuit of a legitimate policy goal."¹³³ In *Japan—Alcoholic Beverages II*, however, the Appellate Body explicitly rejected this aims and effects test, making clear that states were obligated to refrain from favoring domestic products regardless of their motivation.¹³⁴ Affording preferential treatment to domestic goods would violate national treatment even if the state's intent were not protectionist.¹³⁵

129. *U.S.—Section 110(5) Copyright Act*, *supra* note 115, ¶ 6.111 (emphasis added).

130. *Japan—Alcoholic Beverages II*, *supra* note 123; Appellate Body Report, *European Communities—Regime for the Importation, Sale, and Distribution of Bananas*, WT/DS27/AB/R (Sept. 9, 1997) [hereinafter *EC—Bananas III*].

131. *Japan—Alcoholic Beverages II*, *supra* note 123, at 15–16; *EC—Bananas III*, *supra* note 130, ¶ 241.

132. GATT art. III(1).

133. Panel Report, *United States—Taxes on Automobiles*, ¶ 5.10, DS31/R (Oct. 11, 1994). The panel report in *United States—Taxes on Automobiles* was never adopted. Panel Report, *Japan—Taxes on Alcoholic Beverages*, ¶ 6.18, WT/DS8/R, WT/DS10/R, WT/DS11/R (Jul. 11, 1996).

134. *Japan—Alcoholic Beverages II*, *supra* note 123, at 15–16.

135. *Id.* at 27. As the Appellate Body explained:

This is not an issue of intent. It is not necessary for a panel to sort through the many reasons legislators and regulators often have for what they do and weigh the

The different structures of the two treaties suggest panels should be cautious about relying on general GATT jurisprudence in interpreting the TRIPS Agreement. GATT sets out the parties' trade obligations and then provides a general "escape clause" in Article XX that allows countries to vary their obligations to fulfill domestic policy needs. Under Article XX of GATT, states are allowed to adopt and enforce measures that are, among other things, "necessary to protect public morals" or "human, animal or plant life or health."¹³⁶ Thus, in GATT jurisprudence, a panel first considers whether a challenged state action is consistent with the state's trade obligations and only then, if it finds a violation, does it consider whether the action is permitted under Article XX.¹³⁷ Clearly separating these two steps makes sense in the trade context. In GATT disputes, considering the purpose of measures that favor domestic producers would eviscerate the obligation, allowing states to escape liability by demonstrating lack of "intent" to discriminate against foreign products—which would then devolve into complex offers of proof regarding a state's alleged intent. Such an approach would be unworkable in the context of trade, where clear rules provide the predictability needed to ensure the efficient functioning of the global trading system. The state's intent is only relevant later, when considering whether the exception was enacted for a lawful purpose.

The TRIPS Agreement is structured quite differently. Instead of a general escape clause, state parties integrated policy exceptions into the structure and language of the agreement itself. In other words, while GATT provides a system of separate obligations and exceptions, policy flexibility is incorporated directly into the obligations of the TRIPS Agreement. Standard-type norms and explicit exceptions appear throughout the treaty. Two articles specifically directed toward balancing, Articles 7 and 8, are located in Part I of the treaty, entitled "General Provisions and Basic Principles."¹³⁸ This integrated flexibility is essential to intellectual property, an area of law that justifies granting limited monopolies on inventions and cultural goods in order to achieve larger societal goals such as

relative significance of those reasons to establish legislative or regulatory intent. If the measure is applied to imported or domestic products so as to afford protection to domestic production, then it does not matter that there may not have been any desire to engage in protectionism in the minds of the legislators or the regulators who imposed the measure. It is irrelevant that protectionism was not an intended objective

Id.

136. GATT art. XX.

137. Henning Grosse Ruse-Kahn, *Assessing the Need for a General Public Interest Exception in the TRIPS Agreement*, in *INTELLECTUAL PROPERTY RIGHTS IN A FAIR WORLD TRADE SYSTEM*, *supra* note 21, at 167, 187 ("Drafted as a defense, Art.XX GATT comes into play only if a national measure has been found in violation of an obligation under the GATT.").

138. TRIPS Agreement pt. I.

fostering innovation and incentivizing creation.¹³⁹ Panels should be cautious about incorporating GATT approaches into an agreement that so thoroughly integrates policy flexibility.¹⁴⁰

More precisely, however, reliance on *Japan—Alcoholic Beverages II* in *U.S.—Section 110(5) Copyright Act* can be understood as a problem of the right thing in the wrong place. It may in fact be appropriate to rely on GATT jurisprudence at certain points in a TRIPS analysis, but doing so to reject consideration of context in interpreting Article 13 inappropriately imports a legal construct designed to achieve one kind of objective into another meant to do something very different. In evaluating state compliance, both TRIPS and GATT generally anticipate a two-step process—a finding of a violation followed by consideration of exception clauses. Although policy flexibility is integrated throughout rather than presented through a general escape clause, TRIPS adjudicators evaluating exceptions and limitations still must first establish a violation and then determine whether the violation is a permitted exception or limitation.¹⁴¹ Under both treaties, the first step focuses simply on the existence of the violation without regard to policy, while the second is designed to evaluate whether the exception is permitted in light of the purposes it was designed to achieve. In *U.S.—Section 110(5) Copyright Act*, however, the panel imported jurisprudence from a GATT first step into a TRIPS second step. The panel took jurisprudence from a case evaluating the existence of a violation under GATT, which reasonably excludes consideration of intent, into the second step of a TRIPS analysis.¹⁴² The result was to eliminate policy flexibility in this second step and thereby to remove

139. See, e.g., MARGRETH BARRETT, *INTELLECTUAL PROPERTY: CASES AND MATERIALS* 2 (3d ed., 2007) (“The primary purpose of intellectual property law is to ensure a rich, diverse and competitive marketplace.”); CRAIG ALLEN NARD ET AL., *THE LAW OF INTELLECTUAL PROPERTY* 13 (2d ed., 2008) (“Copyrights and patents are something tolerated for the greater societal good.”). Although the natural or moral rights traditions are in some tension with instrumentalist theories of intellectual property, the TRIPS Agreement—which rejects protection of moral rights, see TRIPS Agreement art. 9(1), and specifies the purposes intellectual property rights are intended to serve, see *id.* pmbl. & arts. 7 & 8—would appear to lean more toward the latter than the former.

140. Even in GATT cases, commentators have argued that more consideration of context and a more reasoned approach to balancing are warranted. See, e.g., Horn & Mavroidis, *supra* note 111, at 208 (noting that WTO decisions “are often read in clinical isolation from their context”); Gregory Shaffer & Joel Trachtman, *Interpretation and Institutional Choice at the WTO*, 52 VA. J. INT’L L. 103, 142 (2011) (critiquing the panels’ approach to balancing, noting that in one leading case, the Appellate Body appeared “to proceed by a kind of gestalt,” and that in others, it avoided balancing entirely).

141. See, e.g., *U.S.—Section 110(5) Copyright Act*, *supra* note 115, ¶ 6.13 (observing that the “European Communities bears the burden of establishing a *prima facie* violation of the basic rights that have been provided under the copyright provisions of the TRIPS Agreement, including its provisions that have been incorporated by reference from the Berne Convention” and that “once the European Communities has succeeded in doing so, the burden rests with the United States to establish that any exception or limitation is applicable and that the conditions, if any, for invoking such exception are fulfilled”).

142. See *id.* ¶ 6.111.

consideration of policy concerns from the system of exceptions and limitations in TRIPS.¹⁴³

In eliminating policy considerations, the interpretation of Article 13 in *U.S.—Section 110(5) Copyright Act* is contrary to the text and structure of the treaty and the nature of intellectual property decision making itself. Based solely on the language of the treaty, the phrase “certain special cases” calls for, among other things, consideration of whether the purposes served by the exception make the case “special” or “different” from other cases.¹⁴⁴ Indeed, the *U.S.—Section 110(5) Copyright Act* panel itself defined “special” as “distinctive in some way,” thus inviting comparison between cases, and stated that as a result, “an exception or limitation should be the opposite of a non-special, i.e., a normal case.”¹⁴⁵ This implicit invitation to consider purpose is difficult to harmonize with the panel’s conclusion that the term “special cases” simply means exceptions that are “clearly defined” and “narrow in . . . scope and reach.”¹⁴⁶

The interpretive rules chosen by the parties provide additional support for the argument that they intended the panels to consider context, thereby engaging in some balancing of public and private interests. As Professors Shaffer and Trachtman observe, “states may choose to instruct judges on how to exercise their authority, or they may leave the choice over interpretive rules to the judges.”¹⁴⁷ In the case of the covered agreements, the parties specified interpretive rules. In Article 3(2) of the DSU, members recognize that the WTO dispute settlement system “serves . . . to clarify the existing provisions of those [covered] agreements in accordance with customary rules of interpretation of public international law.”¹⁴⁸ Article 31(1) of the VCLT, which codifies customary norms of interpretation,¹⁴⁹ provides that “[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose.”¹⁵⁰ By choosing customary rules of interpretation, the parties to the TRIPS Agreement can be assumed to have intended the panels to consider the ordinary meaning of the treaty’s terms in light of its object and purpose, including as that object and purpose is laid out in

143. A more appropriate approach would be to use GATT Article XX jurisprudence to interpret TRIPS exceptions and limitations, since these are the respective locations of policy space under these treaties. See *infra* note 218.

144. See Kur, *supra* note 121, at 228 (“The decisive question to be asked in light of further elements to be investigated on the following steps would then be whether the exception is limited enough in view of its purpose and potential impact.”).

145. *U.S.—Section 110(5) Copyright Act*, *supra* note 115, ¶ 6.109.

146. *Id.* ¶ 6.112.

147. Shaffer & Trachtman, *supra* note 140, at 114.

148. DSU art. 3(2).

149. Shaffer & Trachtman, *supra* note 140, at 115.

150. VCLT, *supra* note 128, art. 31(1).

Articles 7 and 8 of TRIPS.¹⁵¹ It is unclear why the *U.S.—Section 110(5) Copyright Act* panel rejected consideration of context when these articles emphasize the importance of the purposes intellectual property policies serve. It is particularly surprising in light of panel and Appellate Body reliance on object and purpose in other cases.¹⁵²

The panel's rejection of approaches that consider context and purpose in interpreting the provisions of the TRIPS Agreement reflects a misapprehension of the task of adjudicators in intellectual property disputes. In the TRIPS Agreement, a good bit of "legislating" has been delegated to the adjudicators. Many of its provisions are "incomplete" contracts—"vaguely specified provisions" that leave the exact scope of obligation "to be decided in the future, when a conflict arises."¹⁵³ The task of completing the contract is left to the adjudicators, and states must "accept the outcome of the ruling as the outcome of the unfinished negotiation."¹⁵⁴ As Frederick Abbott explains, "[t]he TRIPS Agreement was designed to permit a substantial measure of national discretion in its implementation, and adjudicators will not find the broadly drafted provisions of the agreement perfectly instructive in some contexts."¹⁵⁵

Indeed, this gap-filling function is in many ways required by the nature of intellectual property itself. Intellectual property disputes require balancing, since the benefits associated with the limited monopoly granted to rights holders must always be weighed against the externalities that this monopoly can create.¹⁵⁶ The provisions of TRIPS allowing exceptions and

151. Article 7, for example, specifies that intellectual property regulation should contribute to innovation and technology transfer in ways "conducive to social and economic welfare, and to a balance of rights and obligations." TRIPS Agreement art. 7.

152. See, e.g., *EC—Chicken Cuts*, *supra* note 119, ¶¶ 175, 192, 236–250; *Japan—Alcoholic Beverages II*, *supra* note 123, at 11.

153. Horn & Mavroidis, *supra* note 111, at 184.

154. *Id.* at 185.

155. Frederick M. Abbott, *WTO Dispute Settlement Practice Relating to the Agreement on Trade-Related Intellectual Property Rights*, in *THE WTO DISPUTE SETTLEMENT SYSTEM 1995–2003*, *supra* note 98, at 421, 421; see also MATTHIAS OESCH, *STANDARDS OF REVIEW IN WTO DISPUTE RESOLUTION* 47 (2003) ("[O]pen-textured provisions . . . may by nature require to be loosely interpreted and thus may result in some leeway being given to national authorities in the perception of their obligations."); Grosse Ruse-Khan, *supra* note 27, at 61–65 (arguing that ambiguous provisions in the TRIPS Agreement should be interpreted more flexibly and with respect to the treaty's object and purpose).

156. Jon M. Garon, *Normative Copyright: A Conceptual Framework for Copyright Philosophy and Ethics*, 88 CORNELL L. REV. 1278, 1327 (2003) ("The nature of intellectual property requires congressional balancing between copyright holders' interests and other societal interests."); see also Jon O. Newman, *Considering Copyright*, 40 HOUS. L. REV. 613, 615 (2003). Jon Newman, for example, explains:

The dominant issue in all of copyright law is striking an appropriate balance between the maintenance of an adequate incentive for authors to create new works and the vital interest of the public in having adequate access to the works that are created—limited access via the fair use doctrine during the copyright term and general access once the work has entered the public domain.

limitations reflect this need for balance, calling on states to create monopoly rights but giving them options for limiting such rights when necessary to protect other interests. To fully exercise its supervisory function, the WTO dispute resolution system must have the capacity to engage in this balancing as well to determine whether the state was justified in its decision-making process. To interpret the scope of protection under TRIPS, adjudicators must balance the public and private interests affected by copyright in light of the object and purpose of the treaty.

The failure to understand the gap-filling nature of the adjudicator's task in interpreting the TRIPS Agreement may explain in part panels' reluctance to rely on Articles 7 and 8. Although panels have discussed Articles 7 and 8, they have not relied on these provisions directly in interpreting the provisions of the TRIPS Agreement, despite the fact that the VCLT provides that the terms of a treaty should be interpreted in light of the treaty's object and purpose.¹⁵⁷ Instead, the WTO bodies appear to have assumed that the provisions of TRIPS already reflect an appropriate balance between competing concerns. As Susy Frankel argues, panels "look at particular provisions of the Agreement and seem to interpret them as if they incorporate a balance that does not require any additional consideration."¹⁵⁸ As a result, panels inappropriately assume that in interpreting the scope of protection required by the terms of the treaty, there is no need to balance the innovation gains to be achieved by these provisions with the public interests articulated in Articles 7 and 8. For some provisions of the TRIPS Agreement, this is a reasonable assumption. The requirement in the TRIPS Agreement that countries should protect patents for twenty years (as opposed to fifteen or five or thirty) does in fact reflect the parties' agreement on the appropriate balance between patent rights and other social values. For other provisions of the Agreement, however, this balance can only be achieved on a case-by-case basis.¹⁵⁹ Article 13, for example, describes generally the kinds of exceptions

Id. This "tailoring" of domestic innovation policies is one of the several vectors of balancing identified by Graeme Dinwoodie. Graeme Dinwoodie, *The WIPO Copyright Treaty: A Transition to the Future of International Copyright Lawmaking?*, 57 CASE W. RES. L. REV. 751, 754-58 (2007).

157. See Susy Frankel, *WTO Application of "the Customary Rules of Interpretation of Public International Law" to Intellectual Property*, 46 VA. J. INT'L L. 365, 396-97 (2006); see also Peter K. Yu, *TRIPS Enforcement and Developing Countries*, 26 AM. U. INT'L L. REV. 727, 768 ("Although WTO panel reports have applied Articles 7 and 8 on occasion, their application has remained limited, and the two provisions deserve greater attention from both the DSB and members participating in the WTO dispute settlement process.").

158. Susy Frankel, *Some Consequences of Misinterpreting the TRIPS Agreement*, 2009 WORLD INTELL. PROP. ORG. J. 35, 40; see also Frankel, *supra* note 125, at 11 & n.33 ("Panels seem to assume that such a balance has already been dealt with in setting down the standard. This approach, however, ignores the interpretative role of Articles 7 and 8."); Frankel, *supra* note 157, at 397 ("The Panel seems to have suggested that the individual provisions of the TRIPS Agreement reflect the balance and that no other consideration of object and purpose needs to be undertaken.").

159. See, e.g., Grosse Ruse-Kahn, *supra* note 137, at 202-04 (discussing how some provisions of a treaty are more concrete than others and that more ambiguous "provisions

and limitations that are permitted under the Agreement. In applying this provision, it is up to panels and the Appellate Body to determine the appropriate balance based on the facts of each individual case. The need for case-by-case balancing is one of the reasons that the mechanical and formalist reasoning of WTO panels is inappropriate in the TRIPS context.¹⁶⁰

In contrast to the decision in *U.S.—Section 110(5) Copyright Act*, a recent decision in a case brought by the United States against China for violations of the enforcement obligations of the TRIPS Agreement appears to endorse panel consideration of context in ways favorable to developing countries.¹⁶¹ Article 61 of the TRIPS Agreement requires parties to criminalize infringing activities that occur “on a commercial scale.”¹⁶² Relying on Article 1(1), the panel held that TRIPS did not require any particular form of enforcement legislation and that a member will have complied with its obligations as long as it “in fact provides for criminal procedures and penalties to be applied.”¹⁶³ The panel continued: “If it is alleged that a Member’s method of implementation does not so provide in such cases, that allegation must be proven with evidence.”¹⁶⁴ The panel held that the United States had not presented sufficient evidence concerning what constitutes activity on a commercial scale in the relevant markets in China.¹⁶⁵ Thus, at least in interpreting Article 41, it appears that panels will consider context in evaluating what is considered “commercial scale.”

Although a promising step, it is unclear whether this consideration of context will translate into more deferential approaches in cases involving exceptions and limitations. In *China—Intellectual Property Rights*, the panel sought facts about the market, not information about the public interests affected by intellectual property regulation. Making evidence-based determinations about the nature of commercial markets is precisely the kind of thing trade panels do on a regular basis. The panel may have felt more comfortable making this kind of determination than deciding whether a limitation to copyright was necessary in order to protect social or expressive

incorporating *broad and open legal concepts* . . . will not only lend themselves to, but demand an interpretation which draws heavily on, the object and purpose of the international agreement at stake”).

160. See, e.g., Kur, *supra* note 121, at 246 (“[A] mode of interpretation which forecloses any possibility for policy aspects being taken into account is *not compatible* with the object and purpose of TRIPS, as affirmed in the Doha Declaration.”).

161. See Dreyfuss, *supra* note 102, at 16 (arguing that the panel in the *China—Intellectual Property Rights* case demonstrated greater deference to China’s authority than other intellectual property cases decided under the auspices of the WTO); Yu, *supra* note 157, at 744 (arguing that the decision “recognizes the flexibilities retained in the TRIPS Agreement” and “underscores the autonomy and policy space reserved for less developed countries during the TRIPS negotiations”).

162. TRIPS Agreement art. 61.

163. *China—Intellectual Property Rights*, *supra* note 119, ¶¶ 7.601–.602.

164. *Id.*

165. *Id.* ¶¶ 7.614–.629.

values. Thus, the potential influence of the decision may be more limited outside the enforcement context.

III. DESIGNING A STANDARD OF REVIEW FOR IP CASES

Linking intellectual property regulation to the trade dispute mechanism of the WTO has played a significant role in limiting flexibilities protected under the TRIPS Agreement. In part, this is due to the availability of mandatory dispute resolution, which has contributed to a culture of intellectual property overcompliance. This effect has been compounded by the use of interpretive approaches drawn from the trade context. Using trade approaches to interpret the TRIPS Agreement, which is structured very differently, has had the effect of nullifying those portions of the TRIPS Agreement that support the creation of balanced intellectual property protection.

This Part argues that an IP-specific standard of review would help restore the balance envisioned by the TRIPS Agreement. Why a standard of review? The previous Part argued that panels should consider the purpose of exceptions and limitations to intellectual property rights in evaluating their consistency with the treaty. There are, however, a number of decisions about the allocation of interpretive authority necessarily bound up in such an endeavor, including who decides what the purpose is, whether that purpose is a legitimate one, and, at least in the context of copyright, whether the articulated purpose indeed makes the case “special.” Standards of review allocate interpretive authority.¹⁶⁶ A standard of review tailored to the demands of intellectual property balancing will help guide panels in evaluating public policy justifications for exceptions and limitations, allowing them to provide appropriate deference to state policies while nonetheless exercising the supervisory authority vested in them by the TRIPS Agreement.

The appropriate standard of review to be used for any covered agreement must depend on the text of the treaty, read in light of its object and purpose, and the relative competences of local and international decision makers. In light of the text of the TRIPS Agreement and institutional and structural concerns, a standard of review for intellectual property cases should defer to national decision making in evaluating exceptions and limitations to intellectual property rights.

A. *Standards of Review at the WTO*

During the negotiation of the TRIPS Agreement, developing and developed countries disagreed strongly about the standard of review that WTO adjudicators should use with respect to complaints about violations of the

166. Matthias Oesch, *Standards of Review in WTO Dispute Resolution*, 6 J. INT’L ECON. L. 635, 636 (2003) (explaining that standards of review “express a deliberate allocation of power between an authority taking a measure and a judicial organ reviewing it”).

TRIPS Agreement. Developed countries sought a stringent standard. Judith Bello, who was involved in the negotiations on behalf of the U.S. government, recalls that the Bush administration's position with respect to TRIPS "was to empower dispute settlement panelists to scrutinize the measures or practices complained of closely, without undue deference for the member state's findings or determinations underlying them."¹⁶⁷ Developing countries, on the other hand, wanted to cabin the authority of the dispute settlement bodies, arguing that because the TRIPS Agreement required members to limit their sovereignty "more severely than the passive provisions" of the other covered agreements, it was necessary to provide a standard of review "as to the prerequisites under which a panel or the Appellate Body was obliged to respect decisions of the Members."¹⁶⁸

For better or worse, this dispute was never resolved. Members were able to settle on a standard of review for only one of the WTO-covered agreements—the Antidumping Agreement.¹⁶⁹ They were not able to agree on a standard of review for the TRIPS Agreement or any other covered agreement. Oesch and Bello argue that the fact that the parties agreed on a standard of review for one agreement but not others means that they did not intend the panels to defer to state decision making with respect to other types of disputes.¹⁷⁰ More likely, however, failure to agree on a standard of review for disputes under the TRIPS Agreement is simply that—a failure to agree. Since panels would inevitably need to address the appropriate standard of review, failure to agree on such a standard would appear to indicate a decision to delegate to the panels the authority to answer this question.¹⁷¹

167. Judith H. Bello, *Some Practical Observations About WTO Settlement of Intellectual Property Disputes*, 37 VA. J. INT'L L. 357, 362 (1997). With respect to WTO cases in general, states sought "broad review authority" in order to "prevent domestic governments from applying GATT/WTO rules illegitimately to protect domestic industries." Oesch, *supra* note 155, at 75. There was also a concern among states that a deferential standard of review "would necessarily have led to different interpretive approaches as to the meaning of the rules and obligations and thus reduce consistency in the GATT/WTO legal framework." *Id.*; see also Steven P. Croley & John H. Jackson, *WTO Dispute Panel Deference to National Government Decisions: The Misplaced Analogy to the U.S. Chevron Standard-of-Review Doctrine*, in *INTERNATIONAL TRADE LAW AND THE GATT/WTO DISPUTE SETTLEMENT SYSTEM* 187, 194 (Ernst-Ulrich Petersmann ed., 1997).

168. Kaiser, *supra* note 76, at 805; see also Henning Grosse Ruse-Kahn, *Proportionality and Balancing Within the Objectives for Intellectual Property Protection*, in *INTELLECTUAL PROPERTY AND HUMAN RIGHTS* 161, 169 (Paul L.C. Torremans ed., 2008) (observing that it may be particularly important to have a regime that takes account of all interests affected where the intrusion into domestic policies is significant, particularly when accompanied by strong and effective mechanisms of implementation).

169. Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994, art. 17.6, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.N.T.S. 201; see also Bello, *supra* note 167, at 363.

170. Oesch, *supra* note 155, at 54, 75–76, 79; Bello, *supra* note 167, at 362–63.

171. The principle of *non liquet* generally counsels against the filling of gaps by adjudicatory bodies. Richard H. Steinberg, *Judicial Lawmaking at the WTO: Discursive, Constitutional, and Political Constraints*, 98 AM. J. INT'L L. 247, 258 (2004); see also

In the absence of explicit agreement on a standard of review, WTO panels have looked to Article 11 of the DSU¹⁷² for guidance. This article provides that a panel “should make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements.”¹⁷³ Article 11 was not likely intended to provide a standard of review; rather, it appears to have been designed to establish basic due process rights for litigants and “merely requires that there be no bias applied to the adopted standard.”¹⁷⁴ Nonetheless, panels have used this provision to develop a standard of review to be applied in cases other than the Antidumping Agreement.¹⁷⁵ Under the “objective assessment” required by Article 11, panels and the Appellate Body make independent determinations on legal questions.¹⁷⁶ The level of review with respect to factual and policy questions differs for each covered agreement.¹⁷⁷ The panels and Appellate Body have adopted a fairly stringent level of review with respect to most factual questions,¹⁷⁸ although they are somewhat more deferential to some types of decisions involving judgment or political assessment.¹⁷⁹

B. *The Special Case of Intellectual Property*

The WTO adjudicatory bodies have not articulated an explicit standard of review for intellectual property cases. By default, however, their approach in intellectual property cases seems to have been one of *de novo* re-review. By refusing to consider the reasons states offer for the domestic

Frankel, *supra* note 157, at 393–94 (“[Wh]ere the treaty does not favor one object or purpose over another, interpreters of the treaty should not fill the gap and favor one objective.”). On the other hand, the absence of a standard might also “reflect a desire by the signatory nations to leave tough decisions to other institutional arrangements (such as WTO panels) that are subjected to, or insulated from, different political or other pressures.” Dinwoodie, *supra* note 20, at 504. With respect to the standard of review, gap filling seems inevitable if the panels are to fulfill their intended role. Cf. Alec Stone Sweet, *Investor-State Arbitration: Proportionality’s New Frontier*, 4 LAW & ETHICS HUM. RTS. 47, 55 n.19 (2010) (discussing the principle of *Kompetenz-Kompetenz*, which presumes that an arbitrator has the competence “to determine its own jurisdiction, or the jurisdiction of another organ”).

172. OESCH, *supra* note 155, at 75.

173. DSU art. 11.

174. Andrew T. Guzman, *Determining the Appropriate Standard of Review in WTO Disputes*, 42 CORNELL INT’L L.J. 45, 50–51 (2009).

175. See OESCH, *supra* note 155, at 83–85.

176. Guzman, *supra* note 174, at 59; see also OESCH, *supra* note 155, at 174; Claus-Dieter Ehlermann & Nicolas Lockhart, *Standard of Review in WTO Law*, 7 J. INT’L ECON. L. 491, 519–20 (2004).

177. See, e.g., SHARIF BHUIYAN, NATIONAL LAW IN WTO LAW 192 (2007); Ehlermann & Lockhart, *supra* note 176, at 519–20.

178. Guzman, *supra* note 174, at 61–63. See generally OESCH, *supra* note 155, at 119–26, 133–42 (discussing the standard of review panels and the Appellate Body apply to the examination of “raw” factual evidence and factual conclusions).

179. Guzman, *supra* note 174, at 64–67.

intellectual property policies they enact, the panels appear to have determined that no deference is warranted with respect to national decision making. Further, in considering the “legitimate interests” of patent owners and third parties in *Canada—Pharmaceutical Patents*, the panel reserved to itself the authority to determine what interests are “legitimate,” holding that these interests must be “compelling” and “widely recognized” and finding that the interests of the patent owners in the circumstances presented did not meet that standard.¹⁸⁰ As Joost Pauwelyn argues, even if this were a convincing interpretation with respect to the interests of patent owners, it is not clear the panel reached the right decision about who should determine the legitimacy of third party interests:

The same way WTO members have the sovereign right to decide on their own level of health or environmental protection under GATT Article XX exceptions, it should be for WTO members themselves to decide on the nature and extent of these countervailing interests (confirmed, *inter alia*, in TRIPS Articles 7 and 8), even if it may then ultimately be up to a WTO panel to balance these interests against the interests of IP right holders under TRIPS exceptions.¹⁸¹

Thus, the standard of review adopted by the panels thus far in intellectual property cases appears to be *de novo*. Such a standard will not be appropriate in every situation. The challenge for panels, then, is to determine the level of deference required under the terms of the treaty (including for different provisions of the treaty), in light of the treaty’s object and purpose and the relative advantages of local and international decision making.

As an initial matter, it is important to note that different standards of review may be needed across and even within individual covered agreements. In the *EC—Approval and Marketing of Biotech Products* case, for example, the panel explained that the appropriate standard of review “depends on the concrete question at issue and the provisions of WTO law on which a claim is based,” noting that the balance between sovereignty and the jurisdiction of the panel “is expressed differently in different provisions of the covered agreement.”¹⁸² Thus, to the extent that panels develop a standard of review for TRIPS cases, this standard must be tailored to the particular demands of

180. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, ¶ 7.82, WT/DS114/R (Mar. 17, 2000) [hereinafter *Canada—Pharmaceutical Patents*] (finding that the patent owner’s interest in being compensated for limits on the effective term of a patent caused by the need for regulatory review “was neither so compelling nor so widely recognized that it could be regarded as a ‘legitimate interest’ within the meaning of Article 30 of the TRIPS Agreement”).

181. Pauwelyn, *supra* note 1, at 411–12.

182. Panel Report, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, ¶¶ 4.1000–.1001, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sep. 29, 2006) [hereinafter *EC—Approval and Marketing of Biotech Products*]; see also Guzman, *supra* note 174, at 52 (“Article 11 does not, cannot, and should not prescribe a single standard of review for all cases.”).

the individual provisions of the treaty in light of the division of national and international authority they envision.

Several scholars have addressed the question of how much deference WTO bodies should give to national decision making, both in general¹⁸³ and in the context of intellectual property.¹⁸⁴ Broadly, there are three types of considerations relevant to the proper standard of review to be used by international adjudicatory institutions: the terms of the treaty (viewed in light of the treaty's object and purpose), the relative institutional strengths of panels versus states in creating intellectual property policy, and systemic concerns about panel accountability.

First, the level of scrutiny exercised by international adjudicatory bodies must reflect the intent of the parties as manifested in the terms of the treaty. As Susy Frankel argues, panels should defer to national laws "only in those areas where the parties intended to leave the agreement open-textured to allow national interests."¹⁸⁵ Although WTO members did not agree on an overall standard of review for decisions under the TRIPS Agreement, individual provisions do provide guidance. Many of the TRIPS Agreement's obligations are clear and quantifiable, such as the obligation on member states to provide a twenty-year patent term.¹⁸⁶ In such instances, no deference is required. Panels need only ascertain whether the patent term meets the international standard.¹⁸⁷ In other instances, however, deference is built into the terms of the treaty itself. Terms such as "special" (in Article 13), "unreasonabl[e]" (in Articles 13 and 30), and "legitimate" (in Articles 13, 17, and 30) are standard-type norms that Yuval Shany has argued warrant particular deference to national decision making.¹⁸⁸ When the obligations in the treaty impose context-specific standards

183. See, e.g., OESCH, *supra* note 155, at 47; Croley & Jackson, *supra* note 167, at 208–10; Shaffer & Trachtman, *supra* note 140, at 147.

184. See Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 286–97 (1997); Frankel, *supra* note 157, at 393–94; Laurence R. Helfer, *Adjudicating Copyright Claims Under the TRIPS Agreement: The Case for a European Human Rights Analogy*, 39 HARV. INT'L L.J. 357, 432 (1998).

185. Frankel, *supra* note 157, at 393–94; see also *id.* at 428–29 (“[D]eference is appropriate where to do otherwise would ignore the intentions of the parties shown in the Agreement.”).

186. TRIPS Agreement art. 33.

187. This is not to suggest that evaluating compliance with the patent term requirement will always be simple, only that the treaty vests authority to make this determination in the panel, not the state. See Appellate Body Report, *Canada—Term of Patent Protection*, WT/DS170/AB/R (Sept. 18, 2000).

188. Shany, *supra* note 38, at 914–15; see also Grosse Ruse-Kahn, *supra* note 137, at 173, 203–04 (“TRIPS can be interpreted and—more importantly—implemented in [a] manner which should offer a similar amount of policy space for domestic regulation of public interests.”).

such as these rather than specific outcomes, panels should allow states to demonstrate why those standards are met.¹⁸⁹

Deference to national determinations where the text of the treaty indicates such deference is warranted is also consistent with other provisions and subsequent interpretations of the treaty. Article 1(1) of the TRIPS Agreement provides that members “shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”¹⁹⁰ Paragraph 4 of the Declaration on the TRIPS Agreement and Public Health, adopted in conjunction with the 2001 Doha ministerial conference, recognizes the flexibility that member states retain with respect to implementation and “affirm[s] that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”¹⁹¹ Such deference is also consistent with the DSU itself, which states that the “[r]ecommendations and rulings of the [Dispute Settlement Body] cannot add to or diminish the rights and obligations provided in the covered agreements.”¹⁹²

Second, the standard of review must take into account the relative strengths and weaknesses of international versus national decision making. As Andrew Guzman has argued, a standard of review is fundamentally a balance between “the need for objectivity” and “the informational advantage member states possess.”¹⁹³ He explains further that with respect to standards of review for WTO-covered agreements,

189. Under the current jurisprudence of the panels, after the complaining state establishes a *prima facie* case that the defending state has violated a provision of the TRIPS Agreement, the burden shifts to the defending state to demonstrate that the challenged action was permitted under one of the exceptions and limitations protected under the Agreement. See, e.g., *Canada—Pharmaceutical Patents*, *supra* note 180, ¶ 7.16 (holding that once the EC demonstrated a *prima facie* case of violation, the burden shifted to Canada “to demonstrate that the provisions of Sections 55.2(1) and 55.2(2) comply with the criteria laid down in Article 30”); *U.S.—Section 110(5) Copyright Act*, *supra* note 115, ¶ 6.10 (noting that “it is for the European Communities to present a *prima facie* case that Section 110(5)(A) and (B) of the US Copyright Act is inconsistent with the provisions of the TRIPS Agreement” but that “the burden of proving that any exception or limitation is applicable and that any relevant conditions are met falls on the United States as the party bearing the ultimate burden of proof for invoking exceptions”).

190. TRIPS Agreement art. 1(1). Dinwoodie and Dreyfuss characterize this provision as “restat[ing] a fundamental assumption of the international intellectual property system: international norms confine national policy choices, but they do not define them.” Dinwoodie & Dreyfuss, *supra* note 28, at 1217.

191. Declaration on the TRIPS Agreement and Public Health, *supra* note 48, ¶ 4. The Declaration can be considered a subsequent interpretation of the obligations contained in the TRIPS Agreement. See, e.g., Abbott, *supra* note 155, at 445–46 (arguing that the Doha Declaration may be applied as an interpretive source); Yu, *supra* note 6, at 999–1000 (arguing that the Declaration may have an impact on subsequent panel interpretations).

192. DSU art. 3(2); see also *id.* art. 19(2).

193. Guzman, *supra* note 174, at 47–48.

[t]he simple tradeoff between expertise and neutrality can and should guide the determination of appropriate standards of review. On the one hand, where it is possible to evaluate relevant facts using objective criteria and without reference to domestic priorities, panels and the [Appellate Body] should apply a high level of review. Where, on the other hand, there is little risk of bias and a decision requires a great deal of local knowledge, there should be deference to domestic policymakers. In the large number of cases that lie between these two extremes, the standard of review should reflect the relative importance of neutrality and domestic expertise.¹⁹⁴

In the context of intellectual property, many of the decisions panels face will present a significant need for local knowledge, thus counseling a more deferential standard of review. For example, with respect to the standard-type norms of Articles 13, 17, and 30, there is a significant need for local information concerning the nature of the exception, its effect on the rights holder, and the reasons for its implementation. As Yuval Shany has argued, judicial deference is particularly appropriate in such instances of normative uncertainty that require “fact-intensive law-application decisions.”¹⁹⁵ As several commentators have noted, WTO adjudicatory bodies are not well placed to engage in fact finding.¹⁹⁶ Tailoring a domestic intellectual property policy also requires consideration of a range of values not necessarily within the mandate of the WTO, and states—not subject to such limitations—may be better suited to consider these values.¹⁹⁷

Unlike other WTO-covered agreements, the object and purpose of the TRIPS Agreement also renders less acute the risk of protectionism, thus moderating concerns about biased decision making. The TRIPS Agreement differs from other covered agreements because it recognizes that states can, and indeed should, act in ways that are protective of national interests. The preamble and articles of the TRIPS Agreement make clear that intellectual property policy must fulfill dual objectives—not only facilitating trade but also contributing to national goals. The preamble recognizes, for example, that there are public policy objectives underlying national intellectual property systems and that these objectives include development.¹⁹⁸ Article 7

194. *Id.* at 75.

195. Shany, *supra* note 38, at 913.

196. Claus-Dieter Ehlermann, *Six Years on the Bench of the “World Trade Court,”* in *THE WTO DISPUTE SETTLEMENT SYSTEM 1995–2003*, *supra* note 98, at 499, 500; Oesch, *supra* note 155, at 56; Croley & Jackson, *supra* note 167, at 205.

197. Dinwoodie, *supra* note 20, at 511 (noting that the economic orientation of trade law and the WTO dispute process in general means its jurisprudence on intellectual property “might thus develop without full reference to the full set of values that inform its development in national courts throughout the world”).

198. TRIPS Agreement pmbl. (“Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives . . .”).

emphasizes that intellectual property policies “should contribute to the promotion of technological innovation and to the transfer and dissemination of technology.”¹⁹⁹ Article 7 also notes that intellectual property laws should promote innovation to benefit both producers and users “in a manner conducive to social and economic welfare.”²⁰⁰ Thus, the TRIPS Agreement explicitly recognizes that states can and should act in ways that protect and foster domestic interests.²⁰¹

The risks of protectionist conduct are also lower in the intellectual property context because of the more conflicted relationship between intellectual property and trade. Intellectual property is unique among the covered agreements because it can both facilitate and undermine international trade. As Susy Frankel explains, the TRIPS Agreement is designed to protect markets, while GATT and GATS are designed to liberalize access to markets.²⁰² Failure to protect intellectual property can pose a trade barrier if it limits the willingness of foreign investors to invest in a particular country. Intellectual property rights can also be seen as inhibiting trade, however, because they can prevent foreign producers from freely selling their goods on the market. The preamble of the TRIPS Agreement itself states that the WTO members desire “to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.”²⁰³ Because of the more ambiguous connection between intellectual property and trade, domestic intellectual property policies that have the effect of restraining trade are not necessarily in tension with the object and purpose of the TRIPS Agreement.²⁰⁴

Third, there are overall systemic concerns that counsel a more deferential approach to interpreting the TRIPS Agreement. Tailoring domestic intellectual property policies to respond to local needs and concerns often requires making trade-offs between public policy goals—trade-offs that are most legitimate when made by bodies accountable to those who are affected

199. *Id.* art. 7.

200. *Id.*

201. Development is also an objective of other trade agreements, but largely as an expected and intended outcome of reductions in trade barriers. *See, e.g.*, GATT pmb. (stating that members “[recognize] that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living [and] ensuring full employment,” among other things, and expressing members’ desire to contribute to these objectives “by entering into reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade”). Under TRIPS, development is not merely the intended outcome of minimum standards but one of the acknowledged objectives of intellectual property regulation itself.

202. Frankel, *supra* note 125, at 6; *see also id.* at 5 (“While the GATT and GATS agreements have as their overall goal the liberalisation of trade, the protection of intellectual property is a different goal that sometimes works as a trade barrier, rather than a liberalising tool.”).

203. TRIPS Agreement pmb.

204. For a discussion of the risks of protectionism, *see generally* Croley & Jackson, *supra* note 167, at 206; Guzman, *supra* note 174, at 69.

by their decisions.²⁰⁵ Although the WTO adjudicatory bodies are accountable to the states that are members of the organization,²⁰⁶ they are not accountable to the third parties whose interests are likely to be affected by decisions that attempt to balance intellectual property with other national priorities. Especially when the treaty itself requires consideration of the interests of third parties affected by intellectual property regulation, greater deference to national decision makers, who are more likely accountable to such third parties, is warranted.

Developing a standard of review more suited to intellectual property disputes will not eliminate all of the pressure associated with the risk of litigation in the WTO system, nor should it. Rather, such a standard of review would simply moderate the effect that the culture of overcompliance and overly restrictive interpretations of the treaty have had on state willingness to take advantage of TRIPS flexibilities. Requiring additional deference to domestic policies would help restore the balance between public and private interests that was struck in the TRIPS Agreement.²⁰⁷

C. Application to IP Cases

Although the adoption of a standard of review tailored to intellectual property disputes could increase state uncertainty about the outcomes of panel adjudications, the overall result is likely to encourage more experimentation with flexibilities protected under the treaty, thus better approximating the bargain struck between developing and developed nations in the terms of the treaty. A more deferential standard represents a shift in interpretive power to states. By increasing states' interpretive authority, deference would serve as a safe harbor, assuring states that if they actively engage in the process of tailoring their intellectual property policies to local needs, their efforts will be entitled to greater legitimacy. Such an approach would "provid[e] developing country Members that intend to take measures to safeguard access to medicine with . . . security that they will not be dragged into WTO dispute settlement or exposed to pressure by developed

205. Molly Beutz, *Functional Democracy*, 44 HARV. INT'L L.J. 387, 401-02 (2003) (arguing that accountability systems should place decision making in the hands of those affected by the decisions).

206. Croley and Jackson argue against the use of *Chevron*-style deference in the WTO on the ground that the WTO is more accountable than member states. Croley & Jackson, *supra* note 167, at 205. *But see* Dinwoodie, *supra* note 20, at 505 ("[T]he representational legitimacy of the WTO panels is less than ideal"). Balancing, however, primarily affects third parties to whom states, not the WTO, are more likely accountable.

207. Although beyond the scope of this Article, the most likely avenues for implementing a new standard of review may be informal. Between the infrequency of panel decisions on intellectual property issues and "the difficulty of amending or interpreting WTO law through the WTO political process," Shaffer, *supra* note 96, at 470, neither litigation nor amendment are likely to be successful. Informal means might include soft law instruments, expert reports, negotiation, unilateral assertions of policy, and diplomatic exchanges, all of which can foster changes in state practice and help build coalitions around new interpretations.

country Members to adopt more stringent standards required under a different interpretation of the TRIPS Agreement.”²⁰⁸

Although greater deference by panels with respect to state actions that vindicate local public policies is warranted, this deference cannot be unfettered. Both GATT and TRIPS limit the kinds of things states can do in deviating from their principal obligations to protect the public interest. In the GATT context, limits are imposed through the “chapeau” of Article XX, which allows exceptions as long as they do not constitute “arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.”²⁰⁹ The TRIPS Agreement imposes limits through the “consistency clause” of Article 8. Article 8(1), which provides that states may “adopt measures necessary to protect public health and nutrition, and to promote the public interest,” limits this authority to measures that are “consistent with the provisions of this Agreement.”²¹⁰ Although there are a variety of different ways to interpret the consistency clause, giving effect to its terms means at a minimum that states’ ability to use the flexibilities of the treaty cannot be greater than what is permitted under the treaty.²¹¹ Although Susy Frankel has argued that exceptions and limitations should be interpreted more broadly than Article XX of GATT because they do not contain the equivalent of the chapeau,²¹² Article 8(1) likely imposes an equivalent limitation by prohibiting actions inconsistent with the treaty.

Although both treaties require panels to limit exceptions, they provide very different guidance for doing so. The GATT chapeau evidences a primary concern with protectionism. States are entitled to take measures designed to vindicate public policy goals as long as those measures are not applied in a way that constitutes “arbitrary or unjustifiable discrimination” or a “disguised restriction on international trade.”²¹³ Pursuant to Article 8(1) of the TRIPS Agreement, states are allowed to take advantage of the flexibilities of the treaty to protect the public interest as long as they do not exceed the authority of the treaty.²¹⁴ Although the TRIPS Agreement also incorporates the

208. HOLGER HESTERMEYER, *HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES* 230 (2007). As Jerome Reichman argues, “[u]nless public officials in developing countries are willing to stand up for their rights under the TRIPS Agreement and related conventions before the TRIPS Council and, where necessary, in WTO dispute-resolution proceedings, they will not retain the full policy space in which to maneuver that these conventions actually afford.” Reichman, *supra* note 82, at 1177–78.

209. GATT art. XX.

210. TRIPS Agreement art. 8(1).

211. Grosse Ruse-Kahn, *supra* note 137, at 173–80 (summarizing the debate on the “consistency clause” and arguing that it is best understood as limiting exceptions to those enumerated in the treaty and providing an interpretive principle).

212. Frankel, *supra* note 157, at 427.

213. GATT art. XX.

214. TRIPS Agreement art. 8(1).

principle of national treatment,²¹⁵ the consistency clause of Article 8(1) reflects concerns not about protectionism but about scope. In applying the consistency clause, WTO bodies should be concerned not with disguised protectionism but with exceptions to intellectual property that are so broad that they would “swallow the rule” and eviscerate the obligations of the agreement.

Given the need for deference and the importance of ensuring this deference does not eviscerate the obligations of the treaty, how should panels review state actions in the context of the TRIPS Agreement? At least with respect to exceptions and limitations, panels could incorporate limited deference into their decision making by adopting a principle of proportionality. Two years after the formation of the WTO, Larry Helfer argued that panels should draw on the jurisprudence of the European Court of Human Rights in determining the appropriate level of deference to national decision making. Helfer argued that the court provided an appropriate model because of its lengthy experience in grappling with the question of how to exercise international supervision over a treaty that provides states with flexibility in meeting their obligations.²¹⁶ In light of the need for greater balancing in the jurisprudence of the dispute settlement panels, it is a particularly appropriate time to revisit Professor Helfer’s proposal. Drawing on the jurisprudence of the European Court of Human Rights, a panel might consider whether the harm caused by the exception was proportional to the public policy goal to be achieved and whether the means sought were narrowly tailored to achieving that goal.²¹⁷ Exceptions that do not meet these criteria—those that are not proportional or narrowly tailored—would be considered to impose “unreasonable” prejudice.²¹⁸

Panels might also limit the deference afforded state determinations regarding what cases are “special” or what prejudice is “unreasonable” by evaluating these claims against international human rights law and giving greater weight to state actions designed to achieve human rights objectives. For example, a panel might use international human rights law to evaluate a state’s claim that a particular copyright exception was a “special case” that did not impose “unreasonable” prejudice on the copyright owner under

215. See, e.g., *id.* art. 9(1) (incorporating, *inter alia*, Article 5(1) of the Berne Agreement, which establishes a principle of national treatment).

216. Helfer, *supra* note 184, at 363–64.

217. See, e.g., *Salgueiro da Silva Mouta v. Portugal*, App. No. 33290/96, 31 Eur. H.R. Rep. 1055, ¶ 36 (1999) (finding no “reasonable relationship of proportionality” between distinction based on sexual orientation and aim pursued by the state).

218. Requiring measures to be proportional and narrowly tailored would be similar to the “necessity” test used by WTO panels evaluating exceptions in the GATT/GATS context. An exception is “necessary” under Article XX of GATT and Article XIV of GATS if it is designed to achieve a permitted exception and is “the least trade restrictive measure which is reasonably available to the Member State and is equally effective in achieving the desired policy objective.” *Grosse Ruse-Kahn*, *supra* note 137, at 189–90 (emphasis omitted); see *also* *Kur*, *supra* note 121, at 247 (advocating adoption of the Article XX balancing test).

Article 13. An exception or limitation might present a “special” or distinct case if it were created in order to comply with international human rights obligations, and any prejudice imposed in that effort would be less likely “unreasonable.” Such a “human rights presumption” would both control for possible abuses of the deference afforded to state decision making and increase the policy space available to states to tailor intellectual property policies to achieve human rights objectives. In adopting this approach, WTO adjudicatory bodies could look to the decision in *Canada—Pharmaceutical Patents*, in which a panel similarly considered external sources for evidence of legitimacy.²¹⁹ In that case, the panel evaluated the legitimacy of the interest of a patent owner in being compensated for limits on the effective term of a patent due to the need to obtain regulatory approval based on whether this interest was widely recognized in the laws of WTO member states.²²⁰

In adopting a human rights presumption, it is important to note that panels would not be *applying* human rights law. Although nothing explicitly prohibits the WTO from applying non-WTO law in certain situations,²²¹ panels have strictly limited the conditions under which they can consider non-WTO law.²²² Rather, in adopting this presumption, panels would be looking to international human rights law to give content to ambiguous provisions that require consideration of context. Doing so would simply constitute a recognition that the relevant context includes a state’s international obligations to protect human rights. The use of a human rights presumption would preserve the authority of the panel to review state actions but would also guard against arbitrary or overly restrictive review by grounding panel review of state policies in international human rights law.

Article 8 provides additional support for a human rights presumption. Under Article 8, states may adopt measures that are “necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development” or “to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”²²³ In explicitly mentioning state actions designed to protect public health, nutrition, and the overall public interest,

219. *Canada—Pharmaceutical Patents*, *supra* note 180, ¶ 7.82.

220. *Id.*

221. See Joost Pauwelyn, *The Role of Public International Law in the WTO: How Far Can We Go?*, 95 AM. J. INT’L L. 535, 560 (2001) (“[T]he fact that the substantive jurisdiction of WTO panels is limited to claims under WTO covered agreements does not mean that the applicable law available to a WTO panel is necessarily limited to WTO covered agreements.”).

222. See, e.g., Robert L. Howse & Henri Horn, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, 8 WORLD TRADE REV. 49, 55 (2009) (discussing the panel’s decision in *EC—Approval and Marketing of Biotech Products*, *supra* note 182, requiring that “a rule of international law be binding between all the parties of the treaty being interpreted in order to be taken into account in the interpretation of that treaty”).

223. TRIPS Agreement art. 8(1)–(2).

Article 8 not only acknowledges the importance of state intentions in interpreting exceptions and limitations but also presumptively privileges those actions that are designed to further public interest goals. Panels and the Appellate Body can realize the intent of this provision by considering the purposes the exception or limitation is designed to serve and privileging those activities done to further human rights.

Moreover, panels can privilege actions undertaken to achieve human rights goals entirely within the plain meaning of the terms of the treaty. The TRIPS consistency clause in Article 8 limits exceptions and limitations to those enumerated in the treaty by providing that states can take actions to further the public interest, but only to the extent consistent with the treaty—including with the treaty's existing flexibilities.²²⁴ Article 13 allows exceptions constituting “special cases” that do not conflict with the “normal exploitation of the work” and that do not “unreasonably prejudice the legitimate interests of the right holder.”²²⁵ An exception is more likely to meet the terms of the three-step test if it is created to vindicate human rights: such an exception is more likely to be a “special case,” the “normal exploitation of the work” arguably excludes uses that violate human rights, any prejudice associated with the exception is less likely to be “unreasonable,” and rights holders do not likely have “legitimate” interests in causing human rights violations. Thus, panels can protect the public policy goals articulated in Article 8 by considering international human rights law in giving content to ambiguous terms in the treaty.

To better understand the application of a principle of proportionality and human rights presumption, imagine that a state exempts from copyright materials used in primary and secondary school classrooms. It does so in order to address a severe shortage of educational materials in the country. Under this exception, teachers would be allowed to freely supplement the students' textbooks (which may be incomplete or out of date) with handouts or overhead slides in class. The exception was enacted to promote access to educational materials in furtherance of the state's obligations under the International Covenant on Economic, Social and Cultural Rights, which protects the right to education.²²⁶ As interpreted by the Committee on Economic, Social and Cultural Rights, the right to education requires states to “fulfil (provide) the availability of education by actively developing a system of schools, including . . . providing teaching materials.”²²⁷ A panel considering this kind of an exception for classroom

224. Grosse Ruse-Kahn, *supra* note 137, at 174, 194–95. See also *infra* note 229 and accompanying text.

225. TRIPS Agreement art. 13.

226. International Covenant on Economic, Social and Cultural Rights art. 13, *opened for signature* Dec. 19, 1966, 993 U.N.T.S. 3.

227. U.N. Comm. on Econ., Soc. & Cultural Rights, General Comment No. 13, The Right to Education, ¶ 50, U.N. Doc. E/C.12/1999/10 (1999); see also *id.* ¶ 6(a) (noting that “functioning educational institutions and programmes have to be available in sufficient quantity” and observing that although what these institutions require to function may differ

teaching materials under Article 13²²⁸ might conclude that it presents a “special” case because the exception is designed to achieve human rights objectives. The panel might determine that the exception would result in economic prejudice to rights holders, but that such prejudice is not unreasonable given the severe shortage of educational materials and the importance of meeting the state’s human rights obligations. A panel might also find that the state’s chosen measure is proportional to the alleged harm and narrowly tailored to achieve the state’s goal of increasing access.²²⁹

Several others have also proposed alternative interpretive approaches that would create more policy space for states to use TRIPS flexibilities. Henning Grosse Ruse-Kahn and Peter Yu, among others, have proposed interpreting ambiguous treaty language more broadly in light of the object and purpose of the treaty as articulated in Articles 7 and 8.²³⁰ A more deferential standard of review would achieve many of the same goals as these proposals and would function in similar ways, giving more policy space to states in cases of ambiguous treaty provisions. Framing interpretive deference as a standard of review, however, would make clear that a deferential approach is not only one among many acceptable methods of interpretation,²³¹ but one that is required by the terms of the treaty.

depending on context, “all institutions and programmes are likely to require . . . teaching materials”).

228. The state could also make a declaration under the Berne Appendix. The Appendix to the Berne Convention, which was incorporated into the TRIPS Agreement, TRIPS Agreement art. 9(1), allows developing countries to issue compulsory licenses on copyrighted works under certain circumstances. See Berne Convention for the Protection of Literary and Artistic Works app., Sept. 9, 1886, 102 Stat. 2853, 1161 U.N.T.S. 30. The provisions of the Berne Appendix, however, are “so complex and arcane that very few developing countries have been able or willing to take advantage of them.” Chon, *supra* note 9, at 829; see also Daniel J. Gervais, *The Internationalization of Intellectual Property: New Challenges from the Very Old and the Very New*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 929, 941 n.67 (2002) (“Complexity may explain why the [Berne Appendix] system has fallen into disuse.”).

229. This approach would achieve a result similar to the “thumb on the scale” that Margaret Chon articulates in her substantive equality principle, pursuant to which “a decision maker should explicitly consider and defer to a developing country’s stated policy of promoting education for development.” Chon, *supra* note 9, at 844.

230. See, e.g., Grosse Ruse-Kahn, *supra* note 137, at 200–05; Yu, *supra* note 6, at 1022–23; see also Henning Grosse Ruse-Khan, *The (Non) Use of Treaty Object and Purpose in Intellectual Property Disputes in the WTO* 33–34 (Max Planck Inst. for Intellectual Prop. & Competition Law, Research Paper No. 11–15, 2012), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1939859 (discussing the infrequent use of Articles 7 and 8 in WTO adjudication interpreting TRIPS).

231. See VCLT, *supra* note 128, art. 31 (“A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose.”).

IV. DEFERENCE TO LEAST DEVELOPED NATIONS

As the TRIPS transitional periods for least developed nations come to an end,²³² it is an appropriate time to consider the deference afforded to least developed countries in implementing the agreement, particularly in the context of adjudication. The TRIPS Agreement and the DSU, as well as concurrent interpretive statements, indicate the need for these countries to have maximum flexibility in implementing their obligations under the treaty. Panels can provide this flexibility by considering the extent to which intellectual property policies foster development when they interpret standard-type norms in the TRIPS Agreement.

The TRIPS Agreement and concurrent interpretive statements indicate that least developed countries should enjoy maximum flexibility in implementing their obligations under the treaty. The preamble of the TRIPS Agreement specifically recognizes “the special needs of the least-developed country Members in respect of the maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.”²³³ The Decision on Measures in Favour of Least-Developed Countries, a ministerial decision adopted in conjunction with the agreement establishing the WTO and the covered agreements, provides additional support for policies oriented to the needs of least developed nations. The Decision states that least developed countries “will only be required to undertake commitments and concessions to the extent consistent with their individual development, financial and trade needs, or their administrative and institutional capabilities.”²³⁴ The Decision further notes that “[t]he rules set out in the various agreements and instruments and the transitional provisions in the Uruguay Round should be applied in a flexible and supportive manner for the least-developed countries.”²³⁵

This is not to say that least developed countries should be entitled to separate *substantive* standards. The patent term required by the TRIPS Agreement, for example, is twenty years, and this same term applies to developed, developing, and least developed countries.²³⁶ Nor does TRIPS include the kinds of substantive “special and differential” treatment present in other covered agreements.²³⁷ At the same time, the final text of the treaty

232. See *supra* note 37 and accompanying text.

233. TRIPS Agreement pmb.

234. WTO, Ministerial Decision on Measures in Favour of Least-Developed Countries of April 15, 1994, ¶ 1, LT/UR/D-1/3 (1994).

235. *Id.* ¶ 2(iii).

236. TRIPS Agreement art. 33.

237. CONSTANTINE MICHALOPOULOS, SPECIAL AND DIFFERENTIAL TREATMENT OF DEVELOPING COUNTRIES IN TRIPS 2 (TRIPS Issues Papers No. 2, 2003) (noting the “lack of substantial [special and differential treatment]” in the TRIPS Agreement and the problems this poses for developing countries); see Bello, *supra* note 167, at 364 (describing the intent

did retain significant flexibility for country-specific implementation.²³⁸ All of the TRIPS flexibilities described in Part IA of this Article, combined with Article 1(1)'s requirement that states retain discretion in implementation, provide a basis that is more than sufficient for interpreting these common standards in context-specific ways.

In addition, developing countries were able to negotiate explicit consideration of development goals.²³⁹ Among other things, Article 7 requires consideration of the extent to which intellectual property furthers development.²⁴⁰ This does not mean that a country is exempt from TRIPS obligations where these benefits are not being realized. It does suggest, however, that greater deference might be accorded to state policies that limit intellectual property rights in order to achieve the objectives of Article 7. Thus, while the treaty does impose common substantive standards, it also requires that these standards be implemented in ways that foster development objectives.

The DSU also requires particular attention to the needs of least developed countries in adjudication. As I have argued elsewhere,²⁴¹ one of the most important and least well-known provisions of the DSU offering flexibility to least developed countries is Article 24(1). Article 24(1) of the DSU states: "At all stages of the determination of the causes of a dispute and of dispute settlement procedures involving a least-developed country Member, particular consideration shall be given to the special situation of least-developed country Members."²⁴² This "particular consideration" is mandatory, not discretionary,

of the United States in negotiating the TRIPS Agreement to limit "special and differential" treatment in this treaty to transitional periods).

238. MUSUNGU & OH, *supra* note 30, at 4 (noting that developing nations were successful in negotiating "a degree of policy autonomy for governments in relation to the implementation of the Agreement's obligations").

239. The final text of the treaty largely reflects proposals submitted by developed nations, although the language of Articles 7 and 8, which emphasize the development-related purposes of the Agreement, was taken from a proposal by developing countries. Daniel Gervais, *Intellectual Property, Trade & Development: The State of Play*, 74 *FORDHAM L. REV.* 505, 508 (2005) ("The final agreement mirrored the 'A' text. As such, it essentially embodied norms that had been accepted by industrialized countries. The concerns of developing countries were reflected in large part in two provisions—Articles 7 and 8."); *see also* TRIPS RESOURCE BOOK, *supra* note 1, at 123–24; DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 17–19 (1998); Yu, *supra* note 6, at 990–91, 1004.

240. TRIPS Agreement art. 7.

241. *See* Molly Land, *Adjudicating TRIPS for Development*, in *TRIPS AND DEVELOPING COUNTRIES: NEW PERSPECTIVES* (Gustavo Ghidini et al. eds., forthcoming 2012) (manuscript at 10–12) (on file with author).

242. DSU art. 24(1). Although the specific examples provided by Article 24(1) relate to affirmative actions that member states can themselves take with respect to other members, there is no indication that these are exhaustive of the "particular consideration" due to least developed country members. Other provisions of the DSU call for special and differential treatment in consultation, implementation, and adjudication. *See, e.g., id.* art. 3(12) (alternative procedures for consultation), art. 21(2) (special attention in the context of implementation), art. 8(10) (ability to request panelist from developing country).

and explicitly embraces procedures governing the deliberative process. The article requires particular consideration both “[a]t all stages of the determination of the causes of a dispute” as well as “of dispute settlement procedures.” The determination of the causes of a dispute occurs during the hearing itself, when the panel evaluates the reasons for the parties’ dispute and their respective fault. Thus, this phrase specifically contemplates procedures that occur during the hearing itself, such as the use of a more deferential standard of review. Interpreting ambiguous provisions of the TRIPS Agreement to allow consideration of the development objectives of exceptions and limitations and adopting a standard of review that provides particular deference to the decisions of least developed countries in this regard are important ways in which panels could provide “particular consideration” to the needs of least developed countries in dispute settlement.

It is particularly important to consider the extent to which intellectual property policies foster development because such policies may impose more costs than benefits for least developed countries. Although countries in transition, such as Brazil and India, may see gains from strong rights in some instances,²⁴³ recent empirical research indicates that developing countries as a whole may not realize much economic growth through the adoption of strong intellectual property rights.²⁴⁴ Implementation is also more expensive in relative terms for countries with poor legal infrastructure.²⁴⁵ Further, the costs of implementation have largely not been offset by the economic growth, increased foreign direct investment, and technology transfer that proponents of the TRIPS Agreement anticipated.²⁴⁶ Premature adoption of TRIPS Agreement standards, before a country has had the chance to establish a technological infrastructure and creative communities that can take advantage of these standards, may well “put the cost of becoming innovative out of reach.”²⁴⁷ As Carolyn Deere has noted, “For the poorest developing countries . . . there are questions regarding the degree to which IP laws are relevant at all.”²⁴⁸

Because least developed countries benefit so little from the type of intellectual property policies championed by developed countries, different

243. See Dreyfuss, *supra* note 102, at 2–3.

244. Robert L. Ostergard, Jr., *Economic Growth and Intellectual Property Rights Protection: A Reassessment of the Conventional Wisdom*, in INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT, *supra* note 3, at 115, 140.

245. See, e.g., Jean R. Homere, *Intellectual Property, Trade & Development: A View from the United States*, in INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT, *supra* note 3, at 333, 344; Dreyfuss & Lowenfeld, *supra* note 184, at 302–03 (discussing costs of setting up systems to grant, monitor, and enforce intellectual property rights as well as costs associated with loss of comparative advantage).

246. See, e.g., Dreyfuss, *supra* note 102, at 4; Peter K. Yu, *Are Developing Countries Playing a Better TRIPS Game?*, 16 UCLA J. INT’L L. & FOREIGN AFF. (forthcoming 2011) (manuscript at 5) (on file with author).

247. See, e.g., Dreyfuss & Lowenfeld, *supra* note 184, at 303.

248. DEERE, *supra* note 44, at 103.

and greater exceptions and limitations may be required in these countries to create appropriate innovation policies. The extent to which a particular policy supports or hinders development might be considered, for example, in evaluating whether a case is “special” or prejudice is “unreasonable” under the terms of the treaty. A broad fair use doctrine that significantly limits copyright rights with respect to educational materials might not impose an “unreasonable” prejudice on rights holders when the exception is needed to foster development and where there may be little realistic expectation that the educational materials in question would otherwise be purchased by consumers in that market. The approach of the TRIPS Agreement, which integrates deference into the terms of the treaty itself, provides an additional advantage of flexibility. Instead of enabling exceptions based on a country’s classification as “developing” or “least developed,” TRIPS allows panels to consider development objectives based on real economic circumstances. Development needs change, and with time, the conditions that initially necessitated the exception may evolve or even cease to exist.

CONCLUSION

The need for flexibility in implementing the terms of the TRIPS Agreement is clear. Indeed, Peter Yu has argued that the system’s very “legitimacy has been called into question by the high standards of protection and enforcement that ignore the needs, interests, and goals of the less-developed member states.”²⁴⁹ The TRIPS Agreement—by its own terms—does provide states with considerable flexibility in implementation. Yet the decision to link intellectual property standards to mandatory trade dispute resolution has played an important role in constraining policy space for states looking to tailor national intellectual property policies to local needs and conditions. The risk of litigation and overly restrictive interpretations of exceptions and limitations have created a culture of overcompliance that discourages states from testing the flexibilities protected under TRIPS.

The articulation of a more deferential standard of review designed specifically for the TRIPS Agreement, with an emphasis on proportionality and human rights, could help protect the flexibilities that the treaty was designed to provide. Deference is not only consistent with the terms of the treaty but is also necessary to effectuate the intent of the drafters, particularly with respect to least developed countries. In the context of the WTO, such a standard would provide states with the space they need to develop intellectual property regulations tailored to local needs. The very existence of such a safe harbor can encourage states to engage in the kind of experimentation that is necessary for the development of both domestic and international innovation policy.

249. Yu, *supra* note 6, at 1024.

Of course, providing states with additional policy space does not necessarily mean that they will make use of this space to create better policies. As Deere notes, even in countries where debate about intellectual property policy has taken place, “well-organized, pro-IP industry lobbies dominated decision-making processes while consumer groups generally had a ‘weak, diffused, virtually voiceless interest.’”²⁵⁰ Few countries have actually engaged in a deliberative process that has allowed them to weigh the pros and cons of different approaches to intellectual property regulation and their effect on development.²⁵¹ Yet deferring to national decisions with respect to intellectual property policy, even if such decisions are potentially subject to capture, offers at least the possibility of innovation and better approximates the deal struck by member states in the TRIPS Agreement. In addition, providing incentives for states to attempt to balance international obligations with local needs may foster more deliberative national decision making. If panels were to consider the reasons provided by the state for enacting an exception to intellectual property rights, the state has an incentive to engage in reasoned decision making. Evaluating whether the exception is proportional and narrowly tailored to achieving its public policy goal may encourage states to create records that demonstrate consideration of several objectives or reflect negotiations over the scope of the exception. A principle of deference may in this way “push not only for particular substantive outcomes, but also for legitimate domestic processes to achieve those goals.”²⁵²

Finally, the range of arguments presented at the national level would also contribute to the development of international intellectual property norms. With so few intellectual property cases being decided by WTO adjudicatory bodies, increased engagement with and reasoned decision making about these issues on the domestic level would provide an important source of normative content about ways in which states can balance intellectual property rights with other objectives, such as human rights. So conceived, deference might encourage what Dreyfuss and Dinwoodie have called “bottom up” approaches to international intellectual property lawmaking,²⁵³ with

250. DEERE, *supra* note 44, at 206 (citations omitted); *see also* Shaffer & Trachtman, *supra* note 140, at 149 (“[N]ational and sub-national political decision-making processes can be highly problematic from the perspectives of participation, accountability, and global social and political welfare.”).

251. DEERE, *supra* note 44, at 209.

252. Anne-Marie Slaughter & William Burke-White, *The Future of International Law Is Domestic (or, the European Way of Law)*, 47 HARV. INT’L L.J. 327, 348 (2006). In this way, deference may have effects similar to those of the principle of “embeddedness” in the case law of the European Court of Human Rights. Helfer has explained “embeddedness” as a willingness to reach deeply into areas normally reserved to the state in a way that strengthens domestic institutions. *See* Laurence R. Helfer, *Redesigning the European Court of Human Rights: Embeddedness as a Deep Structural Principle of the European Human Rights Regime*, 19 EUR. J. INT’L L. 125, 131–33 (2008).

253. Dinwoodie & Dreyfuss, *supra* note 28, at 1190.

states (again) playing a primary role in generating norms at the intersection of intellectual property and public policy.